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Dear Dr Dhlomo

Comments: National Health Insurance Bill

Contents of Submission

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1. Executive Summary

The South African Medical Technology Industry Association (SAMED), would like to thank the Portfolio Committee for the opportunity to comment on the National Health Insurance Bill B11-2019 (the NHI Bill/the Bill), which has been tabled in Parliament by the Minister of Health. Our comments are included below as well as the Addendums to this document.

Executive Summary of Comments Pertinent to the Medical Technology Industry

1. The principles and objectives of National Health Insurance (NHI) are supported.
2. A well-formulated NHI system is crucial to assist South Africa in advancing universality and social solidarity as the pillars of a patient-centred health system that does not discriminate along economic lines.
3. A staged approach to the implementation of health system reform of the nature proposed in the NHI Bill is supported. A milestone-based implementation plan of NHI aligned with the National Department of Health strategic plan, which is fiscally responsible and approved by National Treasury, as opposed to a time-based plan, is recommended to ensure the successful roll-out of NHI in the best interests of patients.
4. The constitutionality of some of the provisions contained in the Bill is of concern with reference to the rights to freedom of association and to have access to health care services. Any limitation of existing rights must meet the criteria set out in section 36 of the Constitution.
5. It is desirable that the health system reform of the nature that is proposed in the Bill be supported by a clear understanding of the financing model. Care should be taken to prevent possible unintended consequences as a result of, for example, the potential increase in taxes as the main financing mechanism of the system.
6. A Health Technology Assessment (HTA) process is supported to ensure the suitable deployment of medical technology in South Africa. Internationally, HTA is well-entrenched and various models exist, which could be considered by South Africa when designing its own HTA.
7. A fair, transparent and reasonable procurement process is supported in respect of medical technology.
8. It is essential that reimbursement of suppliers is appropriate, reasonable and timeous as this will impact on the availability of suitable and quality medical technology to support patient care of good quality.
9. Accreditation of suppliers should be relevant and provide, amongst others, for the range of products offered by different suppliers, the size of the supplier, geographical distribution and support services being available in all areas. Accreditation should not be administratively burdensome or prohibitive.
10. SAMED does support the opportunity for complementary cover to be purchased as delineated in sections 6(o). Patients should be able to purchase the medical care (including the type of medical technology) that they require with their own money without restriction. Greater clarity of the definition of complementary cover, and the consequences thereof, as mentioned in section 33 is required so as not to create a restriction on private medical schemes, contingent on the scope of benefits offered under NHI.
11. The governance framework of the NHI Fund should be in accordance with best practice standards most notably the King IV Report on Corporate Governance for South Africa 2016 (King IV).
12. The definitions for “medical devices” and “in vitro diagnostics [IVDs]”, which exist in the Medicines and Related Substances Act, should be used in the NHI Bill instead of “health goods” and “health related products”. The term “health products” should be used in the Bill to collectively refer to devices, IVDs, medicines and scheduled substances.
13. It is requested that the overarching legal framework that will govern NHI in South Africa be clarified.

2. Who is SAMED?

SAMED was founded in 1985 and is the voice of the South African medical technology and in vitro diagnostics industry. SAMED represents 185 companies who are responsible for 80% of the revenue generated by the medical technology and in vitro diagnostics industry. SAMED's members include multinationals, distributors, wholesalers and local manufacturers of medical devices, medical equipment and in vitro diagnostics (IVDs) (collectively referred to as 'medical technology') as well as the South African Laboratory and Diagnostic Association (SALDA), the Medical Imaging Systems Association (MISA) and the Medical Device Manufacturers Association of South Africa (MDMSA). Member companies are involved in the manufacture, importation, selling, marketing and distribution of medical technologies in South Africa, which play a vital role across the continuum of patient care, i.e. prevention, screening, diagnosis, treatment and rehabilitation.

3. Contribution of SAMED to the South African Economy

SAMED's members employ more than 4 000 people and cover more than 350 000 different medical technologies used in the diagnosis, prevention, treatment and amelioration of disease and disability. These technologies range from sticking plasters and wheelchairs through to pacemakers, replacement joints and capital equipment such as theatre beds and X-ray machines.

The South Africa medical technology market registered a 9.1% CAGR between 2017-2018 according to a recent Fitch Solutions Report[4] i.e. USD 1.27 billion and is estimated to grow to USD 1.74 billion by 2022. The South African medical technology market by product category in 2018 is demonstrated in the table below.

South Africa Medical Technology Market by Product Category in 2018

Devices	***USD Millions***
Consumables	241.00
Diagnostic Imaging	199.30
Orthopaedics & Prosthetics	153.70
Patient Aids	156.00
Dental Products	41.30
Other Medical Devices	487.10
TOTAL	**1,278.40**

The Fitch Solutions Report indicates there is a limited number of medical devices manufactured in South Africa, therefore the market is largely dependent on imports. Output by the domestic manufacturing industry is estimated to be in the region of USD 200 million - USD 300 million, of which more than half is exported. Local companies, the majority of which are distributors, tend to be small or medium sized businesses with less than 50 employees per business.

4. What is a 'Medical Device' and an 'In Vitro Diagnostic'

Medical technologies are highly variable in nature and include medical devices, medical equipment and IVDs such as wheelchairs, spectacles, hearing aids, plasters, prosthesis, ventilators, heart valves, laboratory tests and x-ray equipment. The following table indicates the various categories of medical devices and IVDs as per the Global Medical Device Nomenclature, an international classification system of medical devices and IVDs:

[4] Fitch Solutions, 2019, South Africa Medical Devices Report. Fitch Solutions, Inc. United Kingdom

Anaesthesia and respiratory devices	Body fluid and tissue management devices
Body tissue manipulation and reparation devices	Cardiovascular therapy devices
Complementary therapy devices	Dental devices
Disability-assistive products	Ear/Nose/Throat (ENT) devices
Endoscopic devices	Gastro-urological devices
General hospital devices	Health care facility products and adaptations
In vitro diagnostic medical devices (IVDs)	Laboratory instruments and equipment
Neurological devices	Obstetrical/Gynaecological devices
Ophthalmic devices	Orthopaedic devices
Physical therapy devices	Plastic surgery and cosmetic devices
Radiological devices	

Definitions for 'medical devices' and 'IVDs' exist in the Medicines and Related Substances Act (Act 101 of 1965), which definitions are entrenched in the health care industry. These definitions are structured to cover all health goods and products other than medicines and scheduled substances. SAMED would like to recommended that these definitions be used in the NHI Bill instead of "health goods" and "health related products". In addition, the term "health products" should be used in the Bill to collectively refer to devices, IVDs, medicines and scheduled substances, where appropriate.

The definitions of "medical device" and "IVD" as included in the Medicines Act are as follows:

"Medical device" is defined as *"any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)-*

(a) intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:
  (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
  (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
  (iii) investigation, replacement, modification or support of the anatomy or of a physiological process;
  (iv) supporting or sustaining life;
  (v) control of conception;
  (vi) disinfection of medical devices; or
  (vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means."

"IVD" (*in vitro* diagnostic) is defined as *"a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human*

body solely or principally to provide information for diagnostic, monitoring or compatibility purposes."

5. Universal Health Coverage

SAMED supports the principles and objectives of NHI in accordance with the Sustainable Development Goals and is keen to support efforts towards their attainment. It recognises the inequities of our current fragmented health care system and the need to improve life expectancy and quality of life of all South Africans. The principles of universality and social solidarity are key to addressing the health care needs of all South Africans. SAMED is of the opinion that a well-formulated NHI is a crucial element that can assist South Africa in advancing universality and social solidarity as the pillars of a patient-centred health system that does not discriminate along economic lines.

The proposed model of NHI for South Africa is unique in that it proposes to integrate two systems, i.e. the public and private health care systems, into a single health system. This would require extensive health system reform. A staged approach to the implementation of health system reform of this nature supported by a detailed implementation plan is called for as it would be more appropriate and not compromise the effectiveness of NHI in the best interests of patients. Any aspect not thoroughly clarified or considered might result in failed implementation with potential detrimental consequences for health care service delivery in South Africa. This could not only have negative consequences for patients, but also impact on the broader economy of South Africa. It is, therefore, recommended that the proposed implementation of NHI as set out in section 57 of the NHI Bill, be milestone-specific, which is fiscally responsible, rather than time-specific. Milestones must also be objectively measurable.

It is acknowledged that both healthcare systems in South Africa face challenges. However, SAMED is of the opinion that combining the two systems into a single funding and delivery model will not necessarily address the ills of the two sectors, which are sought to be addressed. These gaps include barriers to accessing health care services, deficiencies in the quality of care, resource constraints, not being patient centric, deficient infrastructure maintenance, high costs, fraud and corruption. In addition SAMED is concerned that a reduced role for medical schemes, might not address the current barriers to access health care services, which NHI seeks to address, such as out-of-pocket expenses for health care services, distances to health facilities especially in the rural areas, sufficient and qualified human resources to deliver health care services, the maldistribution of health care providers, weak purchasing and incentive schemes, fragmented funding and risk pools and inefficient provider payment mechanisms.

SAMED requests that before the proposed NHI system is implemented, that the Committee should meaningfully engage with all relevant stakeholders and explore tangible, practical implementation plans to achieve universal health coverage. In our opinion, the Presidential Health Summit Compact, is one such an initiative that should be further built upon.

6. Constitutional Considerations

The Constitution and, in particular, the Bill of Rights, guarantee a number of rights and freedoms to individuals. Section 7 of the Constitution stipulates, amongst others, that the Bill of Rights is *"a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom."* Furthermore, the state is obliged *to "respect, protect, promote and fulfil the rights in the Bill of Rights".*

The constitutionality of some of the provisions contained in the Bill is of concern. Although it is acknowledged that any right in the Bill of Rights can be limited, such limitation must meet the criteria set out in section 36 of the Constitution, namely it must be reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom whilst considering all relevant factors. These factors include the nature of the right, the importance of the purpose of the

limitation, the nature and extent of the limitation, the relation between the limitation and its purpose and a less restrictive means to achieve the purpose.

The main rights and freedoms that are of concern are the following:

- Everyone has the right to freedom of association (section 18). Choice is integral to the right to freedom of association. Although the NHI Bill attempts to respect the right of freedom of association by not obliging persons to register as users of the NHI Fund or imposing on service providers and suppliers to obtain contracts with the NHI Fund, this could be an unintended consequence of the Bill in its current form and as such constitute a transgression of section 18 of the Bill of Rights.
- Everyone has the right to have access to health care services (section 27). The State has the obligation to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right. Any mechanism that will reduce access will be unconstitutional. It is submitted that the effect of the current proposals (Section 6(o) and Section 33) might have the unintended consequence of reducing access to health care services instead of progressively increasing access, albeit only for a segment of the population such as those persons who are currently covered by medical schemes.

The Committee is urged to further consider the constitutionality of the Bill in its current form further, so as to prevent a delay in the rollout of NHI.

7. Financing of NHI

It is desirable that health system reform of the nature that is proposed in the Bill be supported by a clear understanding of the financing model. The proposal in the Bill that the system will be funded by additional taxes raises concern. Any imposition of taxes falls within the remit of the Minister of Finance and must be dealt with through a Money Bill. Foreign direct investment may be impacted by prohibitive taxes. The impact of the introduction of any additional taxes must, therefore, be carefully considered for its potential unintended consequences and specifically the impact on all the different stakeholders. It should be noted that the Davis Tax Committee has expressed its reservations in this regard in its report to the Minister of Finance, entitled *Financing a National Health Insurance for South Africa* (March 2017). SAMED recommends that the Portfolio committee consult with the Davis Tax Committee to fully understand the tax implications of the proposed NHI.

To ensure the continued sustainability of the NHI Fund, it is recommended that mechanisms to contain the administrative expenditure of the NHI Fund must be prescribed to ensure that the majority of the funds are used for health care benefits and not for the operational expenditure of the Fund.

8. Health Technology Assessment (HTA)

There are many definitions of HTA. All emphasise its role as a tool supporting decision-making at different level of the health care system, its multi-disciplinary nature and its strong reliance on transparent scientific rigorous methods.

According to the European Network for Health Technology Assessment (EUnetHTA)[1], HTA is a multi-disciplinary process that accumulates and synthesises information about the medical, social, economic and ethical aspects related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient-focused and seek to achieve best value.

The World Health Organisation (WHO) defines HTA as “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 health care, especially on how best to allocate limited funds to health interventions and technologies. The assessment is conducted by interdisciplinary groups using explicit analytical frameworks, drawing on clinical, epidemiological, health economic and other information and methodologies. It may be applied to interventions, such as –

- including a new medicine into a reimbursement scheme;
- rolling-out public health programs (e.g. immunization or screening for cancer);
- priority-setting in health care;
- identifying health interventions that produce the greatest health gain and offer value for money;
- setting prices for medicines and other technologies based on their cost-effectiveness; and
- formulating clinical guidelines."

SAMED supports and endorses the proposal in the NHI Bill that an HTA process is required to ensure the suitable deployment of medical technology in South Africa. SAMED has been actively engaging with stakeholders, most notably the National Department of Health, over many years in an effort to establish an HTA capability for South Africa, which has been lacking in both the public and private health care sectors. Internationally, HTA is well-entrenched and various models exist, which could be considered by South Africa when designing its own HTA. SAMED believes that the HTA capability should be positioned in South Africa for the benefit of both the public and private sectors. Hence, an independent agency performing HTA is supported. This has also been proposed by the Panel of the Health Market Inquiry (HMI) in its final report subsequent to its investigation into the private health sector.

It is submitted that the following principles must underpin an HTA process:

- The establishment of an independent, effective and sustainable HTA agency; and
- An evidenced-based assessment of the cost-effectiveness and efficiency of health technology.

An HTA process should not be costly and lengthy as this would limit patient access to appropriate care. The process should be based on the available clinical evidence, taking into account considerations of cost-effectiveness and affordability, and evaluated periodically to ensure relevance for funding decisions.

Overall there is a dearth of HTA skills in South Africa, required for the establishment and operation of an HTA function.

The proposed Ministerial Advisory Committee on HTA proposed in section 57 of the Bill to serve as a precursor to the HTA agency is noted. However, no information is provided on the composition and decision-making processes of such a Committee. SAMED urges that this be a multi-stakeholder forum with the requisite skills and insights, that operates transparently with regular monitoring and evaluation. It is requested that the Terms of Reference of this Committee be published in the Government Gazette and that a transparent process, which includes nomination of persons with appropriate expertise by stakeholders, must be followed in the establishment of this committee. This recommendation equally applies to all interim Committees proposed to be established in section 57 of the Bill.

9. Procurement

A fair, transparent and reasonable procurement process is supported in respect of medical technology. Although the Bill provides some insight into how health services will be purchased at different levels, it contains no details on how medical technology (devices and IVDs) will be procured, purchased or reimbursed. It should be noted that different conditions (and as such

different medical disciplines) require different technologies for the effective treatment and care of patients. It is essential that the required technology is available at the relevant point of care, which includes primary, secondary, tertiary and quaternary levels.

The role of the local health establishment vis-á-vis the Office of Health Products Procurement, in procurement decisions, ordering and supply is not clear in the Bill. More clarity is required as to who would be authorised to procure from the formulary i.e. who are the contracted health care service providers and health establishments. On a primary care level, clarity is sought on which component of the contracting unit for primary care services (CUPS) would be authorised to procure from the formulary and how procurement would be tracked to ensure reimbursement by the NHI Fund.

The establishment of a formulary to include lists of essential medical devices and other medical technologies is supported on the following conditions:

- A transparent, objective and reasonable process, including an appropriate HTA process, is followed in the determination of these lists.
- Provision is made for procurement from small- and medium-sized medical technology suppliers, including from previously disadvantaged suppliers, whilst acknowledging that some of these suppliers might not have a national capability.
- The process of procurement must be clear and efficient. It must, for example, be clear how frequently a service provider or health establishment could procure from the formulary coupled with appropriate reimbursement arrangements.
- Suppliers must be timeously reimbursed.

It is submitted that the following special features of medical technology must be recognised in the establishment of the procurement process:

- Medical technology is not a commodity. It undergoes rapid cycles of improvement (e.g. every 6 to 24 months) and variation, to meet patient and service provider needs. A procurement process should acknowledge and take into account this product improvement cycle as well as clinical variation in patients' conditions and different patient needs. Moreover, a system that considers price only will fail to account for cost and value over the entire episode of care and will tend to favour older and simpler technology, and may as such eliminate models with benefits for meeting different clinical and patient needs.
- Medical technology often relates to more than selling of individual items, but rather to integrated / interwoven solutions e.g. software with data management, medical equipment with consumables, after sales service, maintenance and training.
- Medical technology is complex. Hence an approach tailored to accommodate sub-specialities of devices, rather than trying to group products into broad categories, is advisable. For example, external fixators, divided into upper and lower limbs, sterile versus non-sterile and single-use versus reusable medical technologies.
- Competitive procurement should support and recognise the value of innovation in medical technology to patients, clinicians and the health care system, and should reward features that bring new capabilities and improved efficiencies and options to the clinical pathway.
- Medical devices often remain implanted in a patient or in use at a hospital for many years. Much of the cost and economic value of medical devices is not only the purchase price but also the quality, service, technical support, training and education provided by the supplier and the value it adds to the patient's life, quality of life and life expectancy over the years. In the case of implantable devices, much of the service and support comes subsequent to implantation. Extra hospital procedures to replace or adjust low-quality devices add greatly to overall costs. To be cost efficient, a procurement process must take overall value into account over the duration of the patient's clinical condition.
- Medical equipment maintenance is critical. A supplier may offer a good price, but not provide any maintenance services or spare parts as part of the contract. In certain instances, particular

consumables/disposables associated with the medical equipment are needed on an ongoing basis and a supplier should be willing to provide such products and support services for the duration of the contract.

- There must be alignment in procurement between the responsible parties as capital equipment and consumables are not always interchangeable.
- To meet different service provider and patient needs, medical technology procurement contracts should not be exclusive, but should allow for participation of multiple models and types where feasible.
- Many conditions require the availability of a variety of medical devices. For example, patients differ in size, age, co-morbidities and may require specific devices. There should be alternatives available for such patients.
- Expenditure on innovative and appropriate medical technology can free resources to provide greater health care coverage to growing populations. Provision should be made for the introduction of new technology.
- Appropriate and efficient purchasing and procurement are critical to the success and sustainability of the health system. An effective system is one which has the correct medical equipment, consumables and implants at the point of service delivery i.e. available to allow for immediate patient care.
- There is a perception that central procurement of medical technology items is a panacea to drive down the costs of technology in health care. SAMED believes that centralised procurement may also have shortcomings that need to be considered:
    - An efficient and cost-effective central procurement process requires one national data base of all medical items, which is continuously updated regarding stock levels at every health care facility. Procurement without such a system is known to cause extreme shortages (stock-outs) or over-supply. Stock-outs make it impossible for health care facilities to deliver contracted services and over-supply leads to excessive carrying costs. In the former scenario, performance-based remuneration or incentives for health care providers will not be feasible, and the latter scenario will be wasteful.
    - The maintenance of equipment is critical for quality health care and value on investment. Districts may have different burdens of disease and different demographics. This would require variance in the procurement and maintenance needs.
    - Many devices require direct training of staff and commitments to ensure product maintenance and similar technical support (e.g. availability of spare parts and technicians), which are best arranged and provided locally, and not centrally.

Procurement in the public health care sector is currently managed and controlled by National Treasury. It is not clear how the proposed procurement system in the NHI Bill will be aligned with the existing processes and systems in view of the establishment of the Office of Health Products Procurement within the office of the NHI Fund. The Central Supplier Database (CSD), which is managed by National Treasury, works well. It is recommended that the CSD be maintained in the future system.

SAMED would like to encourage a review of international markets to establish a best practice in the procurement of medical technology. A number of productive and functional models exists within these international markets, and the recommendation is to consider these well-established practices and processes to allow for a fully functional procurement system. SAMED is willing to engage with the NHI Fund to share these insights and information. Addendum 2 to this submission contains a high-level summary of some of the models in operation internationally.

10. Reimbursement

It is essential that reimbursement of suppliers is appropriate, reasonable and timeous as this will impact on the availability of suitable and quality medical technology to support patient care of good quality. SAMED supports the following reimbursement principles in respect of medical technology:

- **The medical technology industry is unique.** Hence, processes, methodologies and expertise used in pharmaceutical evidence appraisals, are not always applicable to medical devices and no single approach should be applied to the diversity of medical technology in multiple service delivery settings.
- **Transparency.** Reimbursement policies should be vetted and implemented in an open process, in which the decision-making criteria and process for implementation are fully disclosed in advance to stakeholders.
- **Timing, notice and comment.** The NHI Fund and any entity authorised to implement procurement policies should provide ample time and opportunity for stakeholders - including members of the public - for notice and comment on the proposed policies.
- **Stakeholder role and input.** The NHI Fund and any entity authorised to implement procurement processes should be required to disclose and discuss the input provided and consider this input in finalising benefit and reimbursement decisions.
- **Consistency.** The NHI Fund and any entity authorised to implement procurement should attempt to adhere to a predictable schedule for proposed updates and/or system reforms.
- **Best value.** A payment system should recognise the resources needed to deliver a group of services, or entire episode of care. The resources should be from well-established clinical guidelines, reflect the long-term value of medical technology and not focus on short-term costs.
- **Use market competition to evaluate the domestic price of the product.** There should be an acknowledgement that market forces are allowed to operate to maximise efficiency and improve patient care.
- **Reward innovation.** There should be an acknowledgement that systems and resources are needed to encourage innovation, which provides continuous progress in patient outcomes.

Price alone is not an indicator of quality, need or appropriateness of any technology and does not recognise the services required to support the technology. SAMED, therefore, does not support the requirement in the NHI Bill (Section 11) that the NHI Fund must "negotiate the lowest possible prices for goods and health care services". It is, however, recognised that price could be a factor once the appropriateness of a medical technology for a particular patient has been confirmed.

Furthermore, it is not clear in the NHI Bill how medical technologies that have been procured by health care service providers and health establishments would be reimbursed.

11. Accreditation

The NHI Bill provides for the accreditation and contracting of suppliers. However, there is no indication of what the accreditation requirements, process and period of accreditation for suppliers entail. The definition of "accredited" in section 1 of the NHI Bill refers to section 39, which is only applicable to service providers. SAMED would like to submit that accreditation of suppliers should be relevant and provide, amongst others, for the range of products offered by different suppliers, the size of the supplier, geographical distribution and support services being available in all areas. Furthermore, accreditation should not be administratively burdensome or prohibitive and should take into account the information currently being collected and reviewed by SAHPRA in respect of medical device and IVD establishments.

12. Role of Medical Schemes

SAMED supports a dispensation in which persons are able to choose how and where they spend their private money. Furthermore, national health systems across the world exist alongside private health systems. Hence restrictions on the cover that medical schemes or other private health insurance schemes may offer is not supported. In a free market economy such restrictions are not appropriate. As the HMI report has indicated, competition promotes better health outcomes. The rationale for imposing a restriction on the ability of medical schemes to offer parallel cover to the NHI Fund is not clear. It should be noted that SAMED's opposition to the proposed role for medical schemes should not be construed as opposition to the principles of universal health coverage.

13. Governance of the NHI Fund

The proposed governance structure of the NHI (Chapters 4 to 7 of the Bill) raises concerns. In addition, to not meeting the standards of good corporate governance as recommended, amongst others, in the King IV Report on Corporate Governance 2016 (King IV), it will also entrench significant political power which is to be avoided in the context of the current economic challenges created by political interference at State-owned entities. To avoid irregular expenditure, wastage and qualified audits, sufficient focus must be placed on good governance and the achievement of desired outcomes. Structures must be implemented that ensure checks and balances, transparency and public input.

The involvement of the Minister of Health with decision-making at all levels of the NHI Fund is not in accordance with good corporate governance principles. In terms of the proposals, the Minister will not only have authority over all the senior appointments, including the members of the Appeal Tribunal, but he will essentially be in control of benefit design and be able to influence procurement, as well as the accreditation and contracting of all public and private practitioners and facilities that will deliver the services under NHI – all critical elements in the operationalisation of universal health coverage. The granting of extensive powers to the Minister has the effect of making key decisions subject to arbitrary political decision-making. The governance of State-owned enterprises is a case in point where effective management of these entities are too often frustrated by political interference. Legal requirements and clinical elements of the system must be rational, objective and transparent and not open to political interference.

It is therefore recommended that a sufficiently independent and accountable Board should be appointed. A transparent process should be followed to appoint Board members. Although a public nomination process for board members will seemingly be followed, the specific skills that must be represented on the board have not been defined. Due to the critical functions and responsibilities of the Board, it is essential that the relevant skills and experience that will be required on the Board are specified and it should be ensured that members have the required skills and experience. It is consequently recommended that an independent judicial panel should be responsible for the nomination process and appointment of Board members. Furthermore, provision should be made for staggered rotation of Board members to ensure continuity and mitigate against governance failure.

It is also advisable in terms of good corporate governance standards that the governing body, i.e. the Board of the NHI Fund, should be in control of the organisation's, i.e. the NHI Fund's, functions relative to its object and purpose. In this regard, the Board of the NHI Fund must have the power to establish committees that are required for the fulfilment of its key functions, i.e. purchasing of health care services and payment of such services. According to the Bill, the Benefits Advisory Committee and the Health Services Pricing Committee will be appointed by and function under the auspices of the Minister of Health. It is submitted that the design of the NHI benefits should be a Fund responsibility. The Bill only makes provision for the Fund to determine best practices related to benefit design. This must be rectified. The Health Care Benefits Pricing Committee, will make recommendations on prices for the health care benefits to the Fund. This will result in a situation where the governing body, i.e. the Board, will be obliged to offer the benefits designed by an external committee, i.e. the Ministerial Benefits Advisory Committee, irrespective of the costs of those benefits. This has the potential to drive prices of goods and services to unsustainable levels and undermine value-based procurement based on clinical insight. In addition, there is insufficient provision for the relative sizes, appointment processes and mandates of the various 'Ministerial Committees' in the Bill. Committee members must have expertise across all aspects of health care service benefits, including medical technology, and pricing.

As to the powers and functions of the Board, it is recommended that the Board must be responsible for all decisions regarding the strategic positioning and operationalisation of the NHI Fund, including the appointment of the chief executive officer and key committees. The board must also be duty-

bound to ensure that the Fund is conducted in a financially sustainable manner. Should the reserves fall below the statutory specified minimum (as contemplated to be stipulated in Regulations), provision must be made for obligatory remedial action. As a principle of good governance explicit provision should be made for the NHI Fund to outsource any relevant function should the Board determine it to be the best option in the circumstances.

SAMED supports the efforts against corruption and towards good governance. In this regard, SAMED applauds the overt desire to "preclude or limit undesirable, unethical and unlawful practices in relation to the NHI Fund". Our progress as a nation has been blighted economically, by corruption and this needs to be eradicated if we are to achieve the real potential of the rainbow nation. Section 16, which seeks to prohibit any conflict of interest by Board members, section 20(3)(i) which establishes a Risk and Fraud Prevention Investigation Unit to deal with fraud and corruption within the NHI Fund, and section 24, which requires the disclosure of interests of members of technical committees, are noble in intent.

14. Legal Framework

It is very difficult for stakeholders to understand the complete regulatory framework that will govern the envisaged NHI system and to make meaningful comment. The reason for this is first and foremost the fact that a significant number of details of the proposed system are still outstanding, most notably the financing model, the contents of the benefits package and the details of the procurement process. Furthermore, in addition to the NHI Bill currently before the Portfolio Committee, of which the Schedule contains proposed amendments to 11 laws, which will have a significant impact on the roll-out of NHI, the Presidential Health Compact as well as the Report of the HMI have recently been released. In our view, many more laws will require amendment to facilitate the full implementation of NHI. SAMED hereby requests that the overarching legal framework of the proposed NHI system be clarified and made available. It is proposed that the various laws be amended through Bills that follow the prescribed legal process for comment instead of proposing amendments to key laws in the Schedule to the Bill.

Furthermore, although it is understood that the Bill contains only enabling provisions, and that many of the details will be included in Regulations, SAMED would like to request the Committee to facilitate the publication of the draft Regulations under the Bill for stakeholders to obtain a comprehensive understanding of the entire legal framework that will govern NHI. SAMED requests that the legislature should engage persons with expertise in the various fields to ensure the preparation of an informed set of Regulations, which consider all relevant aspects of the proposed system. The Committee is also requested to ensure that stakeholders are provided with sufficient time to comment on these Regulations. SAMED also opposes the exclusion of the Competition Act from the NHI Bill.

15. Engagement with SAMED

Medical devices and IVDs play a vital role across the continuum of patient care (prevention, screening, diagnosis, treatment and rehabilitation). As such the medical technology sector plays a significant role in providing effective and efficient health care for all South Africans and could be a significant enabler for the roll-out of the NHI. SAMED therefore requests recognition and distinction of the medical technology industry from the pharmaceutical industry. SAMED also requests to be included in all engagements and consultation with the health care industry by the NHI Fund, its related structures and the National Department of Health in respect of the planning, implementation and monitoring of NHI.

16. Analysis of the NHI Bill

A detailed analysis of all the provisions of the NHI Bill, including recommendations for amendment and suitable alternatives, where appropriate, is attached to this letter as Addendum 1.

17. Public Hearings: Verbal Submission

SAMED would like to request the opportunity to engage further with the Committee on its submission and therefore request an opportunity to make a verbal submission during the public hearings in Parliament.

18. Conclusion

SAMED recognises the inequities of the current fragmented health care system and is an eager partner in the mission to improve the nation's health care and health outcomes. SAMED will continue to mobilise support within its sector and the broader society for universal health care and NHI. SAMED would like to emphasise its commitment to participate in finding a way to effectively address the health care needs of all South Africans.

Yours sincerely

Tanya Vogt
SAMED Executive Officer

Addendum 1:

Name of Organisation / Individual:	**SAMED: The South African Medical Technology Industry Association**
Date of submission:	**29 November 2019**
Contact:	**Tanya Vogt, SAMED Executive Officer** **Email: tanya@samed.org.za**

GENERAL EXPLANATORY NOTE:
[ ] Words in bold type in square brackets indicate omissions from existing enactments.
Words underlined with a solid line indicate insertions in existing enactments.

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
BILL			
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			

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Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
limit undesirable, unethical and unlawful practices in relation to the Fund and its users; and to provide for matters connected herewith.			
PREAMBLE			
RECOGNISING—			
• the socio-economic injustices, imbalances and inequities of the past;			
• the need to heal the divisions of the past and to establish a society based on democratic values, social justice and fundamental human rights; and			
• the need to improve the quality of life of all citizens and to free the potential of each person;			
1. 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;			
• the right to bodily and psychological integrity is entrenched in section 12(2) of the Constitution;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
• in terms of section 27(1)*(a)* of the Constitution everyone has the right to have access to health care services, including reproductive health care;			
• in terms of section 27(2) of the Constitution the State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of the right of access to health care services;			
• in terms of section 27(3) of the Constitution no one may be refused emergency medical treatment; and			
• section 28(1)(c) of the Constitution provides that every child has the right to basic health care services;			
1.1 **AND IN ORDER TO—**			
• achieve the progressive realisation of the right of access to quality personal health care services;	It is of concern that the bill has downgraded the level of service to users from ‘’good quality’ to ‘quality’.	The is a need for consistency in quality standards. There should be no compromise in compliance to quality and regulatory standards	We propose that there be consistency in the standard of both services and goods that patients’ access within NHI. It is recommended that the standard should be to achieve ‘good’ quality. Replace all references to quality with ‘good’ quality.
• make progress towards achieving Universal Health Coverage;	South Africa has already made significant progress in providing access to health care through government funded health care facilities. There are already channels with local and provincial		

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	government for patients to receive medical care.		
• ensure financial protection from the costs of health care and provide access to quality health care services by pooling public revenue in order to actively and strategically purchase health care services based on the principles of universality and social solidarity;			
• create a single framework throughout the Republic for the public funding and public purchasing of health care services, medicines, health goods and health related products, and to eliminate the fragmentation of health care funding in the Republic;			
• promote sustainable, equitable, appropriate, efficient and effective public funding for the purchasing of health care services and the procurement of medicines, health goods and health related products from service providers within the context of the national health system; and			
• ensure continuity and portability of financing and services throughout the Republic,			
BE IT THEREFORE ENACTED by the Parliament of the Republic of South Africa, as follows:—			
Sections			
ARRANGEMENT OF ACT			
1. Definitions			
Chapter 1			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
PURPOSE AND APPLICATION OF ACT			
2. Purpose of Act			
3. Application of Act:			
Chapter 2			
ACCESS TO HEALTH CARE SERVICES			
4. Population coverage			
5. Registration as users			
6. Rights of users			
7. Health care services coverage			
8. Cost coverage			
Chapter 3			
NATIONAL HEALTH INSURANCE FUND			
9. Establishment of Fund			
10. Functions of Fund			
11. Powers of Fund			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Chapter 4			
BOARD OF FUND			
12. Establishment of Board			
13. Constitution and composition of Board			
14. Chairperson and Deputy Chairperson			
15. Functions and powers of Board			
16. Conduct and disclosure of interests			
17. Procedures			
18. Remuneration and reimbursement			
Chapter 5			
CHIEF EXECUTIVE OFFICER			
19. Appointment			
20. Responsibilities			
21. Relationship of Chief Executive Officer with Minister, Director-General and Office of Health Standards Compliance			
22. Staff at executive management level			
Chapter 6			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
COMMITTEES TO BE ESTABLISHED BY BOARD			
23. Committees of Board			
24. Technical committees			
Chapter 7			
ADVISORY COMMITTEES ESTABLISHED BY MINISTER			
25. Benefits Advisory Committee			
26. Health Care Benefits Pricing Committee			
27. Stakeholder Advisory Committee			
28. Disclosure of interests			
29. Procedures and remuneration			
30. Vacation of office			
Chapter 8			
GENERAL PROVISIONS APPLICABLE TO OPERATION OF FUND			
31. Role of Minister			
32. Role of Department			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
33. Role of Medical Schemes			
34. National Health Information System			
35. Purchasing of health care services			
36. Role of District Health Management Office			
37. Contracting Unit for Primary Health Care			
38. Office of Health Products Procurement			
39. Accreditation of service providers			
40. Information platform of Fund			
41. Payment of health care service providers			
Chapter 9			
COMPLAINTS AND APPEALS			
42. Complaints			
43. Lodging of appeals			
44. Appeal Tribunal			
45. Powers of Appeal Tribunal			
46. Secretariat			
47. Procedure and remuneration			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Chapter 10			
FINANCIAL MATTERS			
48. Sources of funding			
49. Chief source of income			
50. Auditing			
51. Annual reports			
Chapter 11			
MISCELLANEOUS			
52. Assignment of duties and delegation of powers			
53. Protection of confidential information			
54. Offences and penalties			
55. Regulations			
56. Directives			
57. Transitional arrangements			
58. Repeal or amendment of laws			
59. Short title and commencement			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
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;			
''ambulance services'' means ambulance services as contemplated in Part A of Schedule 5 to the Constitution;			
''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;	The cost of research can be significant and thus research and training conducted by private hospitals should also be recognized. These hospitals can add value as they have the infrastructure and capacity in		**''central hospital''** means a public <u>and private</u> 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

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	conducting training and research. This could be in the form of a PPP. Private hospitals have been excluded from this definition "Central Hospitals". There needs to be some way to still allow private hospitals to be		excellence for conducting research and training of health workers;
''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;			
''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;	The definition of "complementary cover" is problematic if read with other sections of the Bill related to services 'not reimbursable' by the NHI Fund. It is difficult to comment on these aspects in isolation. SAMED suggests there a section dealing with complementary cover, cover of medical schemes, etc. Need to define personal healthcare service benefits under "complementary cover"		<u>Insertion of a definition for "personal health care service benefits" to refer to health services provided to individual users.</u> Personal Health Care Service Benefits are health care services which are taken within a patient's private capacity as opposed to that which takes place under the instruction of an

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
			HCP or within the setting of an HCO.
''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;			
''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;			
''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;			
''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;			
''financial year'' means a financial year as defined in section 1 of the Public Finance Management Act;			
''Formulary'' means the Formulary and its composition referred to in section 38(4);			
''Fund'' means the National Health Insurance Fund established by section 9;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
''health care service'' means—			
(a) health care services, including reproductive health car and emergency medical treatment, contemplated in section 27 of the Constitution;			
(b) basic nutrition and basic health care services contemplated in section 28(1)*(c)* of the Constitution;			
(c) medical treatment contemplated in section 35(2)*(e)* of the Constitution; and	Section 35(2)(e) provides as follows: "(*e*) to conditions of detention that are consistent with human dignity, including at least exercise and the provision, at state expense, of adequate accommodation, nutrition, reading material and medical treatment."		
(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;			
''health establishment'' means a health establishment as defined in section 1 of the National Health Act;	A "health establishment" also refers to a health care practice. For clarity purposes, a health care practice should		

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	be excluded from the definition of “health establishment” as it is included under “health care service provider”.		
‘‘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;			
‘‘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;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
''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);			
"medical device" means medical device as defined in Section 1 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);	Medical devices are not defined in the Bill and SAMED suggests that like medicines, the definition as per the Medicines and Related Substances Act be included i.e. "**medical device"** means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)— (a) intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:		**"medical device"** means medical device as defined in Section 1 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	(i) diagnosis, prevention, monitoring, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; (iii) investigation, replacement, modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) control of conception; (vi) disinfection of medical devices; or (vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and (b) which does not achieve its primary intended action [in		

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	or on the human body] by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;''		
''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;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
''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—	Propose include palliative services as this is a basic human right.		**''primary health care''** means addressing the main health problems in the community through providing promotive, preventive, curative, palliative 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 health care 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;	The word ''care"' appears to have been omitted from primary allied health professionals		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 care allied health professional, through multi-disciplinary practices;
''procurement'' has the meaning ascribed to it in section 217(1) of the Constitution;	Procurement needs to be better defined as Section 217(1) states: When an organ of state in the national, provincial or local sphere of government, or any other		

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	institution identified in national legislation, contracts for goods or services, it must do so in accordance with a system which is fair, equitable, transparent, competitive and cost-effective."		
''Promotion of Access to Information Act'' means the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000);			
''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;	in a way that creates appropriate incentives might be misinterpreted as perverse		**''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;
''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;	The definition of referral requires amendment as it is currently defined with reference to section 44(2) of		**''referral''** means the transfer of a user to an appropriate health establishment **[in terms of**

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	the National Health Act, it only refers to transfers between public health establishments. This is inappropriate as it excludes private health establishments which is against the spirit and intention of the NHI Bill. It is consequently proposed that the following words be removed from the definition: "in terms of section 44(2) of the National Health Act".		**section 44(2) of the National Health Act]**;
''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;	It is unsure what is meant by "active" purchasing? Please consider a definition to ensure clarity. Health good must also be included with services as not only services will be		**''strategic purchasing''** means the active purchasing of <u>health goods and</u> health care services by the pooling of funds and the purchasing of comprehensive health care services from

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	purchased by the Fund. The definition must be aligned with section 2(c) where the term is used.		accredited and contracted providers on behalf of the population;
A "**supplier**" means a natural or juristic person in the public or private sector providing goods and services other than personal health services. This includes companies that manufacture, wholesale, retail, distribute or import health products.	Definition for "supplier" is required. It is proposed to insert the definition of "supplier" after "strategic purchasing":		A "**supplier**" means a natural or juristic person in the public or private sector providing goods and services other than personal health services. This includes companies that manufacture, wholesale, retail, distribute or import health products.
''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			
Purpose of Act			
2. The purpose of this Act is to establish and maintain a National Health Insurance Fund in the Republic funded through mandatory prepayment that aims to achieve sustainable and affordable universal access to quality health care services by—			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(a) serving as the single purchaser and single payer of health care services in order to ensure the equitable and fair distribution and use of health care services;			
(b) ensuring the sustainability of funding for health care services within the Republic; and			
(c) providing for equity and efficiency in funding by pooling of funds and strategic purchasing of health care services, medicines, health goods and health related products from accredited and contracted health care service providers.			
Application of Act			
3. (1) This Act applies to all health establishments, excluding military health services and establishments.			
(2) This Act does not apply to members of—			
(a) the National Defence Force; and			
(b) the State Security Agency			
(3) If any conflict, relating to the matters dealt with in this Act, arises between this Act and the provisions of any other law, except the Constitution and the Public Finance Management Act or any Act expressly amending this Act, the provisions of this Act prevail.			
(4) The Act does not in any way amend, change or affect the funding and functions of any organs of state in respect of health care services until legislation contemplated in sections 77 and 214, read with section 227, of the Constitution and any other relevant legislation have been enacted or amended.			
(5) The Competition Act, 1998 (Act No. 89 of 1998), is not applicable to any transactions concluded in	Exclusion of oversight by the competition commission		The Competition Act, 1998 (Act No. 89 of 1998), is **[not]**

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
terms of this Act.	under the Competition Act could allow for potential abuse of dominance or horizontal collusion.		applicable to any transactions concluded in terms of this Act.
Chapter 2			
ACCESS TO HEALTH CARE SERVICES			
Population coverage			Section 4(1) should be subject to the persons excluded from benefits as contemplated in section 3
4. (1) The Fund, in consultation with the Minister, must purchase health care services, determined by the Benefits Advisory Committee, on behalf of—			
(a) South African citizens;			
(b) permanent residents;			
(c) refugees;			
(d) inmates as provided for in section 12 of the Correctional Services Act, 1998 (Act No. 111 of 1998); and			
(e) certain categories or individual foreigners determined by the Minister of Home Affairs, after			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
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)*(c)* of the Constitution.			
4. A person seeking health care services from an accredited health care service provider or health establishment must be registered as a user of the Fund as provided for in section 5, and must present proof of such registration to the health care service provider or health establishment in order to secure the health care service benefits to which he or she is entitled.			
5. A foreigner visiting the Republic for any purpose—			
a. must have travel insurance to receive health care services under their relevant travel insurance contract or policy; and			
(b) who does not have travel insurance contract or policy referred to in paragraph, has the right to health care services as contemplated in subsection (2)			
Registration as users			
5. (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.			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(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.			
(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			
(c) 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)*(e)*.			
(7) Unaccredited health establishments whose			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
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.			
(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.			
Rights of users			
(6) Without derogating from any other right or entitlement granted under this Act or under any other law, a user of health care services purchased by the Fund is entitled, 10 within the State's available and appropriated resources—			
(a) to receive necessary quality health care services free at the point of care from an accredited health care provider or health establishment upon proof of registration with the Fund;	Internationally aligned measures and standards must be identified, adhered to and published in order to ensure quality health care services.		
(b) to information relating to the Fund and health care service benefits available 15 to users;			
(c) to access any information or records relating to his or her health kept by the Fund, as provided for in the Promotion of Access to Information Act, in order to exercise or protect his or her rights;			
(d) not to be refused access to health care services on unreasonable grounds;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(e) not to be unfairly discriminated against as provided for in the Constitution and the Promotion of Equality and Prevention of Unfair Discrimination Act, 2000 (Act No. 4 of 2000);			
(f) to access health care services within a reasonable time period;	Unclear as to what is considered a 'reasonable time period'	People have different interpretations of what is considered 'reasonable'. South Africa should aim to meet globally accepted standards of health care provision. Without a clear understanding of what is considered a 'reasonable time period', users could be subject to prolonged waiting periods for time sensitive treatments and even emergencies.	to access health care services <u>within published time periods aligned with globally accepted standards</u>;
(g) to be treated with a professional standard of care;			
(h) to make reasonable decisions about his or her health care;			
(i) to submit a complaint in accordance with section 42 regarding—			
(i) poor access to or quality of health care services; or			
(ii) fraud or other abuses by a health care service provider, a health establishment, a supplier or the Fund;			
(j) to request written reasons for decisions of the Fund;			
(k) to lodge an appeal against a decision of the Fund in accordance with section 43;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(l) to institute proceedings for the judicial review of any decision of the Appeal Tribunal;			
(m) to the protection of his or her rights to privacy and confidentiality, in accordance with the Protection of Personal Information Act, 2013 (Act No. 4 of 2013), in so far as he or she must grant written approval for the disclosure of personal information in the possession of or accessible to the Fund, unless the information—			
(i) is shared among health care service providers for the lawful purpose of serving the interests of users; or			
(ii) is utilised by the Fund for any other lawful purpose related or incidental to the functions of the Fund;			
(n) to have access to information on the funding of health care services in the Republic; and			
(o) to purchase health care services that are not covered by the Fund through a complementary voluntary medical insurance scheme registered in terms of the Medical Schemes Act, any other private health insurance scheme or out of pocket payments, as the case may be.	Refer to the comment at section 33.		Definition to be deleted.
Health care services coverage			
7.(1) Subject to the provisions of this Act, the Fund, in consultation with the Minister, must purchase health care services, determined by the Benefits Advisory Committee, for the benefit of users.	There is no reason why the Minister should be consulted by the Fund for this purpose.		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.

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(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;	This can only refer to primary health care services. Users will register with primary health care service providers. They can only render services within their competency and experience,		a user must receive the health care services that he or she is entitled to under this Act from a primary 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;			
c. should a health care service provider or health establishment contemplated in paragraph *(a)* or *(b)* not be able to provide the necessary health care services, the health care service provider or health establishment in question must transfer the user concerned to another appropriate health care service provider or health establishment that is capable of providing the necessary health care services in such manner and on such terms as may be prescribed;			
d. a user—			
i. must first access health care services at a primary health care level as the entry into the health system;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
ii. must adhere to the referral pathways prescribed for health care service providers or health establishments; and	Concern regarding the constitutionality of this. Users being forced to only access specific referral pathways given by their primary health provider. Reconsider the frameworks of referral pathways available to users, so as to allow freedom of choice with regards to onward referrals.	This prevents the user, the right to choose and talks to the state limiting access to health care services under Section 7(2) of the constitution. Patients have the right to choose their health care provider in terms of the National Patients; Rights Charter.	
iii. is not entitled to health care services purchased by the Fund if he or she fails to adhere to the prescribed referral pathways;	Refer to comment at section 33.		
(e) the Fund must enter into contracts with accredited health care service providers and health establishments at primary health care and hospital level based on the health needs of users and in accordance with referral pathways; and	The position of medical specialists and health care practitioners other than primary care practitioners must be clarified.		
(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;	If the national government retains the budgeting function, the envisaged control over financial		

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	management and establishment of cost centres envisaged in (iii) and (iv) will be severely hampered. Governance structures should be suitable and focused on good governance outcomes as contemplated in King IV. This includes accountability of the governing body.		
(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—			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(a) no medical necessity exists for the health care service in question;	Medical necessity must be objectively determinable by the health care service provider or health establishment that must provide the services failure of which will result unnecessary and unworkable bureaucratic processes before users with be able to access needed health care services or know that they must fund these services on an out-of-pocket or medical scheme basis.		
(b) no cost-effective intervention exists for the health care service as determined by a health technology assessment; or			
(c) the health care product or treatment is not included in the Formulary, except in circumstances where a complementary list has been approved by the Minister.	The governing body is accountable and must determine what should be funded or not. Relevant persons may be consulted.		the health care product or treatment is not included in the Formulary, except in circumstances where a complementary list has been approved by the Fund.
(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;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(c) consider the representations made in respect of paragraph *(b)*; and			
(d) provide adequate reasons for the decision to refuse the health care service to the user.			
(6) A user who is dissatisfied with the reasons for the decision contemplated in subsection (5)(d) may lodge an appeal in terms of section 43.			
Cost coverage			
8. (1) A user of the Fund is entitled to receive the health care services purchased on his or her behalf by the Fund from an accredited health care service provider or health establishment free at the point of care.	This should include health goods.		A user of the Fund is entitled to receive the health care services or health goods 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;	Need to include health goods		(2) A person or user, as the case may be, must pay for health care services or health goods rendered directly, through a voluntary medical insurance scheme or through any other private insurance scheme, if that person or user—
(b) fails to comply with referral pathways prescribed by a health care service provider or health establishment;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(c) seeks services that are not deemed medically necessary by the Benefits Advisory Committee; or	Refer also to the comment under sections 7(1) and 7(4)(a) above.		
(d) seeks treatment that is not included in the Formulary.			
Chapter 3			
NATIONAL HEALTH INSURANCE FUND			
Establishment of Fund			
9. The National Health Insurance Fund is hereby established as an autonomous public entity, as contained in Schedule 3A to the Public Finance Management Act.			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Functions of Fund			
10. (1) To achieve the purpose of this Act, the Fund must—			
(a) take all reasonably necessary steps to achieve the objectives of the Fund and the attainment of universal health coverage as outlined in section 2;			
(b) pool the allocated resources in order to actively purchase and procure health care services, medicines, health goods and health related products from health care service providers, health establishments and suppliers that are certified and accredited in accordance with the provisions of this Act, the National Health Act and the Public Finance Management Act;			
(c) purchase health care services on behalf of users as advised by the Benefits Advisory Committee;			
(d) enter into contracts with accredited health care service providers based on the health care needs of users;			
(e) prioritise the timely reimbursement of health care services to achieve equity;			
(f) establish mechanisms and issue directives for the regular, appropriate and timeous payment of health care service providers, health establishments and suppliers;			
(g) determine payment rates annually for health care service providers, health establishments and suppliers in the prescribed manner and in accordance with the provisions of this Act;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(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;	SAMED supports procurement from accredited suppliers. For Medical Device companies this is already achieved by licencing under the Medicines Act. Ensure compliance with and prevent duplication with already existing accreditation / certification legislation. There needs to be greater clarity on kind of accreditation will be required of suppliers. If accreditation is required, who will do that accreditation? Recognition of the existing accreditation bodies such as SAHPRA for health goods.		

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(k) ensure that health care service providers, health establishments and suppliers are paid in accordance with the quality and value of the service provided at every level of care;			
(l) monitor the registration, license or accreditation status, as the case may be, of health care service providers, health establishments and suppliers;	See same comment under 10(j)		
(m) account to the Minister on the performance of its functions and the exercise of its powers;	Account to the board instead of the Minister to reduce extensive political power through the minister.	The board has oversight over the performance of the management (fund)	account to the **[Minister]** board on the performance of its functions and the exercise of its powers;
(n) undertake internal audit and risk management;			
(o) undertake research, monitoring and evaluation of the impact of the Fund on national health outcomes;			
(p) liaise and exchange information with the Department, statutory professional councils, other government departments and organs of state as and when appropriate or necessary in order to achieve the purpose outlined in section 2;			
(q) maintain a national database on the demographic and epidemiological profile of the population;			
(r) protect the rights and interests of users of the Fund;			
(s) enforce compliance with this Act;			
(t) take any other action or steps which are incidental to the performance of the functions or the exercise of the powers of the Fund; and			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(u) operate in accordance with the provisions of this Act and other applicable lawat 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.			
(3) The Fund performs its functions in accordance with health policies approved by the Minister.	National health policy is determined in terms of the National Health Act.		The Fund performs its functions in accordance with health policies approved in accordance with **[by]** the [**Minister**] National Health Act.
(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.			
Powers of Fund	Please refer to covering comments regarding governance		
11) 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;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(c) sell, lease, mortgage, encumber, dispose of, exchange, cultivate, develop, build upon or improve, or in any other manner manage, its property;			
(d) in the prescribed manner and subject to national legislation, invest any money not immediately required for the conduct of its business and realise, alter or reinvest such investments or otherwise manage such funds or investments;			
(e) draw, draft, accept, endorse, discount, sign and issue promissory notes, bills and other negotiable or transferable instruments, excluding share certificates;			
(f) insure itself against any loss, damage, risk or liability which it may suffer or incur;			
(g) improve access to, and the funding, purchasing and procurement of, health care services, medicines, health goods and health related products that are of a reasonable quality;	The Bill generally refers only to “quality”. “Reasonable quality” is not an acceptable standard. Refer also to our comments at [insert general comment that we made with regards to international standards] above.	What is currently available in the health system should be improved. Hence the objective should be to obtain goods and services of quality based on international standards [ref previous comment].	improve access to health care services, medicines, health goods and health related products that are of **[a reasonable]** quality;
(h) investigate complaints against the Fund, health care service providers, health establishments or suppliers;			
(i) identify, develop, promote and facilitate the implementation of best practices in respect of—			
(i) the purchase of health care services and procurement of medicines, health goods and health related products on behalf of users;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(ii) payment of health care service providers, health workers, health establishments and suppliers;	Include a definition of health workers.		
(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;	The designation of referral networks should be done by qualified individuals within the Fund. Failure to do so could compromise patient outcomes.		
(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;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(l) obtain from, or exchange information with, any other public entity or organ of state;	This must be subject to legislation applicable to the sharing of information		obtain from, or exchange information with, any other public entity or organ of state subject to any laws applicable to such information, i.e. POPIA
(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;	Needs to include health establishments and suppliers.		conclude an agreement with any person for the performance of any particular act or particular work, or supply of health goods, or the rendering of 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.			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(2) The Fund may enter into a contract for the procurement and supply of specific health care services, medicines, health goods and health related products with an accredited health care service provider, health establishment or supplier, and must—			
(a) purchase such services of sufficient quantity and quality to meet the needs of users;			
(b) take all reasonable measures to ensure that there may be no interruption to supply for the duration of the contract;			
(c) conduct its business in a manner that is consistent with the best interests of users;			
(d) not conduct itself in a manner that contravenes this Act; and			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(e) 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.	Lowest price doesn't imply value. Value is a composite of direct and indirect costs beyond the initial purchase price. Other costs to be considered are those related but not limited to installation, maintenance, life cycle, training, upgrade, calibrations, quality controls and recovery time. Additional indirect costs to be considered include societal and economic costs such as loss of productivity and travel time. The "lowest possible price" has the potential to create inflexibility and might not be conducive to the circumstances	Other factors need to be considered when evaluating price points, in accordance with health technology evaluations and evidence-based outcomes. Other factors need to be considered under effective health technology management, such as service and maintenance of equipment.	negotiate the [**lowest possible**] <u>most cost-effective</u> price for goods and health care services without compromising <u>the quality of its services,</u> the interests of users or violating the provisions of this Act or any other applicable law.
Chapter 4			
BOARD OF FUND			
Establishment of Board			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
12. A Board that is accountable to the Minister is hereby established to govern the Fund in accordance with the provisions of the Public Finance Management Act.	The accountability of the Board to the Minister is of concern. It is essential that the board of the NHI fund should be, and should be seen to be independent. The Minister holds extraordinary powers on the constitution of the board: The Board should be accountable to the users of the Fund.	The accountability to establish the Board should sit with parliament or an independent judicial panel rather than an individual. **Concern is raised regarding the governance of State-owned enterprises. Effective management** of these entities are too often frustrated by political interference. There needs to be adequate checks and balances in place to prevent this. A credible, relevant Board fit for purpose is required. The Governance framework of the fund is extremely concerning, especially viewed in the light of the rampant state capture at Transnet and Eskom, which had similar governance structures in place.	"A Board that is accountable to **[the Minister]** Parliament is hereby established to govern the Fund in accordance with the provisions of the Public Finance Management Act.

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		There is too little oversight of the powers provided to the minister and the risk for patronage in such as system, should a Minister prove to have questionable morality, can be devastating to the South African Healthcare system. This is especially worrying, as the budget for the NHI Fund is projected to be significant. It is vital that the appointment of the board, CEO, procurement officer, chief financial officer, etc. are done at arm's length to the state. The NHI cannot emulate other SOEs and needs transparent appointment processes.	
Constitution and composition of Board			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
13. (1) The Board consists of not more than 11 persons appointed by the Minister who are not employed by the Fund and one member who represents the Minister.	It is unclear if the person representing the Minister part of the 11? Or is this person in addition to the 11? It is submitted that the Board does not require a representative of the Minister. Board members must be appointed on the basis of their experience and expertise and no other basis.	A credible, relevant Board fit for purpose is required.	The Board consists of [**not more than 11**] 12 persons appointed by the Minister <u>on account of their expertise and experience</u> 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—	There should be a clear understanding of how the advisory panel will be appointed. It must be people with appropriate knowledge and expertise who can assess the persons in terms of the needs of the Fund and all users of the Fund.	Concerns regarding effective governance, and oversight could be perceived should a transparent process not be followed. Clarification regarding the appointment of the panel, reflecting the appropriate skills and knowledge is requested.	

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(a) conduct public interviews of shortlisted candidates; and	Clarification is required as to who will be responsible to shortlist candidates. Shortlisted candidates should be published for public commentary.		
(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—	The proposed term of 5 years does not allow for good corporate governance. Losing all skills and acquired expertise at a single point would be detrimental to the Fund.	Provision must be made for staggered rotation to ensure continuation of the Board in terms of good corporate governance, and to ensure continuity of the Fund.	A Board member is appointed for a term not exceeding five years, <u>the rotation of selection will be staggered accordingly</u>, which is renewable only once, and must—
(a) be a fit and proper person;	“Fit and proper” must be defined. Disqualifications of board members should be similar that of directors under the Companies Act. The disqualifications must either be listed or the Companies Act referenced.	A definition of ‘fit and proper’ needs to be indicated.	be a fit and proper person; <u>any disqualifications will be in accordance with the Companies Act.</u>

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(b) have appropriate technical expertise, skills and knowledge or experience in health care service financing, health economics, public health planning, monitoring and evaluation, law, actuarial sciences, information technology and communication;			
(c) be able to perform effectively and in the interests of the general public;			
(d) not be employed by the State; and			
(e) not have any personal or professional interest in the Fund or the health sector that would interfere with the performance in good faith of his or her duties as a Board member.	Persons who have any conflict of interest or any potential conflict of interest should be disqualified from serving on the Board.		not have any personal or professional interest [**in the Fund or the health sector**] that would conflict or interfere with the performance of his or her duties as a Board member.
(6) The Chief Executive Officer is an ex officio member of the Board, but may not vote at its meetings.			
(7) A Board member may resign by written notice to the Minister.			
(8) The Minister may remove a Board member if that person—			
(a) is or becomes disqualified in terms of any law;			
(b) fails to perform the functions of office in good faith, in the public interest and in accordance with applicable ethical and legal prescripts; or			
(c) becomes unable to continue to perform the functions of office for any other reason.			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(9) (a) Subject to paragraph (b), the Minister may dissolve the Board on good cause shown only after—	The circumstances under which the Board may be dissolved must be listed e.g. if the Fund becomes insolvent, corruption, etc. It should not be a Ministerial decision.	Transparent governance in reference to the fund is imperative for sustainability.	Include a clause to allow for transparency regarding dissolution of the Board.
(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.	There should be a clear understanding of how any acting board members will be appointed. It must be people with appropriate knowledge and expertise who can assess the persons in terms of the needs of the Fund and all users of the Fund.	Concerns regarding effective governance, and oversight could be perceived should a transparent process not be followed. Clarification regarding the appointment of any acting board members reflecting the appropriate skills and knowledge is requested.	
Chairperson and Deputy Chairperson			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
14. (1) The Minister must appoint a Chairperson from amongst the members of the Board as contemplated in section 13(1).	The Minister should not have any involvement in the appointment of the Board chair. In terms of good governance practices the Board should elect a chairperson from its number at its first meeting.	The appointment by the minister could call into question the appropriateness of the appointment.	In accordance with good corporate governance, we recommend the following change *The Board must appoint a Chairperson from amongst it's members, as contemplated in section 13(1).; this appointment should take place at the first meeting of the Board.*
(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.			An indication must be provided as to how long a temporary Chairperson or Deputy Chairperson may be appointed for, in the absence of the Chairperson or Deputy Chairperson.

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Functions and powers of Board	The powers of the Board are not comprehensive enough. As the Board, it must be in control of the fund and be responsible for steering the Fund. It must play a leadership and strategic role. It is advisable that the functions and duties as contemplated in the King Code of Corporate Governance (King IV) should be included in the Board's remit. The Board must also have the power to delegate functions without abdicating its responsibility.		Include the functions and duties contemplated on the King Code of Corporate Governance in the outline of the Board's functions and powers.
15. (1) The Board must fulfil the functions of an accounting authority as required by the Public Finance Management Act and is accountable to the Minister.	It is a Schedule 3A entity. It should therefore not be accountable to the Minister. The Auditor-General should audit the accounts.		*The Board must fulfil the functions of an accounting authority as required by the Public Finance Management Act and all annual audits should be submitted to the Auditor General in accordance with legislation.*

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(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.	No provision is made for staggered rotation of the Board, which means that it is possible that when their terms (2 terms of 5 years each) expire, an entirely new board will be appointed. This will impact continuity and could result in significant governance failure.		Allow for provision of staggered rotation of Board members to allow for continuity and functionality of the NHI.
(3) The Board must advise the Minister on any matter concerning—			
(a) the management and administration of the Fund, including operational, financial and administrative policies and practices;			
(b) the development of comprehensive health care services to be funded by the Fund through the Benefits Advisory Committee;			
(c) the pricing of health care services to be purchased by the Fund through the Health Care Benefits Pricing Committee of the Board;			
(d) the improvement of efficiency and performance of the Fund in terms of strategic purchasing and provision of health care services;			
(e) terms and conditions of employment of Fund employees;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(f) collective bargaining;	Collective bargaining which does not compromise the quality of health care and supports improved patient outcomes It should be clarified what the collective bargaining refers to.		Change to: Collective bargaining which does not compromise the quality of health care and supports improved patient outcomes.
(g) the budget of the Fund;			
(h) the implementation of this Act and other relevant legislation; and			
(i) overseeing the transition from when this legislation is enacted until the Fund is fully implemented.			
(4) For the purposes of subsection (1), the Board—			
(a) may examine and comment on any policies, investigate, evaluate and advise on any practices and decisions of the Fund or the Chief Executive Officer under this Act;			
(b) is entitled to all relevant information concerning the administration of the Fund;			
(c) may require—			
(i) the Chief Executive Officer to submit a report concerning a matter on which the Board must give advice; or			
(ii) any Fund employee to appear before it and give explanations concerning such a matter; and			
(d)must inform the Minister of any advice it gives to the Chief Executive Officer.			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Conduct and disclosure of interests			
16. (1) A member of the Board may not engage in any paid employment that may conflict with the proper performance of his or her functions.	As recommended in section 5 (e) any conflict of interest or potential conflict of interest should result in disqualification. It is recommended that a conflict of interest, as well as a related party, be defined in the Bill.	A conflict of interest occurs when there is a direct or indirect conflict, in fact or in appearance, between the interests of a member of the Board and that of the Fund. It applies to financial, economic, and other interests in any opportunity from which the Fund may benefit, as well as use of the property of the Fund, including information. It also applies to the related parties of the member of the Board holding such interests.	Provide definition of what is considered a 'conflict of interest' as well as a definition for 'related party'.
(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	If a member has any conflict of interest, he must be disqualified from acting as a Board member. Refer to the		

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	comments above in Section 16 (1).		
(c) make private use of, or profit from, any confidential information obtained as a result of performing his or her functions as a member of the Board.	Confidential information should be defined.		Provide definition of 'Confidential information'
(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.	This should be included in the definition of a conflict of interest.		Provide inclusion of the term 'Financial interest' in the definition of 'Conflict of Interest'.
Procedures			
17. The Board must determine its own procedures in consultation with the Minister			
Remuneration and reimbursement			
18. The Fund may remunerate a Board member and compensate him or her for expenses as determined by the Minister in consultation with the Minister of Finance and in line with the provisions of the Public Finance Management Act.			
Chapter 5			
CHIEF EXECUTIVE OFFICER			
Appointment			
19. (1) A Chief Executive Officer must be appointed on the basis of his or her experience and technical competence			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
as the administrative head of the Fund in accordance with a transparent and competitive process.			
(2) The Board must—			
(a) conduct interviews of shortlisted candidates; and	There should be provision made that the Board can determine its own procedures and processes in this regard e.g. eth appointment of a Nomination Committee who can recommend candidates to the Board for interview. Clarification is required as to who will be responsible to shortlist candidates. Shortlisted candidates should be published for public commentary.	The process should allow for good corporate governance.	The Board must publish the list of shortlisted candidates and perform interviews of potential candidates.
(b) forward their recommendations to the Minister for approval by Cabinet.	The Board must be able to appoint the CEO and not the Cabinet. The Board could consult with the Minister, if required.	Good corporate governance.	The Board must, after consultation with the Minister, appoint a suitably qualified person as the Chief Executive Officer of the Fund.
(3) The Minister must, within 30 days from the date of appointment of the Chief Executive Officer, notify Parliament	This is Board's responsibility.	Good corporate governance.	The Board must, within 30 days from the date of appointment of the Chief Executive Officer, notify

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
of the final appointment and give notice of the appointment in the Gazette.			Parliament of the 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—	The Board must remove the CEO on certain specified grounds e.g. serious misconduct, conflict of interest, undermining the integrity of the Fund.	Good corporate governance.	The Board, will enforce the removal of the Chief Executive Officer, in consultation with the Minister, 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			
(c) becomes unable to continue to perform the functions of his or her office for any other reason.			
Responsibilities	.		

Clause / section		Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
20.	(1) The Chief Executive Officer as administrative head of the Fund—	The CEO must conclude a performance agreement with the Board.		
(a)	is directly accountable to the Board;			
(b)	is responsible for the functions specifically designated by the Board;			
(c)	takes all decisions as contemplated in terms of subsection (6); and	There are no decisions specified in subsection (6)		Remove this clause.
(d)	must report to the Board on a quarterly basis and to Parliament on an annual basis.	Include requirements for regular reporting on the fund's performance to the relevant authority(ies), for example, National Treasury, Parliament etc		
(2)	Subject to the direction of the Board, the responsibilities of the Chief Executive Officer include the—			
(a)	formation and development of an efficient Fund administration;			
(b)	organisation and control of the staff of the Fund;			
(c)	maintenance of discipline within the Fund;			
(d)	effective deployment and utilisation of staff to achieve maximum operational results; and			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(e) establishment of an Investigating Unit within the national office of the Fund for the purposes of—	This could be combined with subsection 3. Refer to subsection (3)(i). There should not be different units with similar functions.		Align clause in subsection (3) (i)
(i) investigating complaints of fraud, corruption, other criminal activity, unethical business practices and abuse relating to any matter affecting the Fund or users of the Fund; and			
(ii) liaising with the District Health Management Office concerning any matter contemplated in subparagraph (i).			
(3) Subject to the direction of the Board, the Chief Executive Officer must establish the following units in order to ensure the efficient and effective functioning of the Fund:			
(a) Planning;			
(b) Benefits Design;			
(c) Provider Payment Mechanisms and Rates;	.		
(d) Accreditation;			
(e) Purchasing and Contracting;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(f) Provider Payment;	Duplication of duties under subsection (3) (c)		Remove
(g) Procurement;	This unit will overlap with the establishment of the Office of Health Products Procurement contemplated in section 38. Governance structure to be aligned.		
(h) Performance Monitoring; and	The CEO of the fund should ensure that all senior managers of the NHI Fund and other structures should have a KPI based on the outcomes of the Auditor General's annual report.	Performance can only be tracked if measured and reported on. Regular reporting and monitoring will ensure timeous correction of irregularities or inefficiencies.	
(i) Risk and Fraud Prevention Investigation.	There appears to be an overlap with the unit contemplated in subsection (2)(c)		Align with subsection (2) (e)
(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;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(c) all assets and the discharge of all liabilities of the Fund; and			
(d) the proper and diligent implementation of financial matters of the Fund as provided for in the Public Finance Management Act.			
(5) The Chief Executive Officer must submit to the Board an annual report of the activities of the Fund during a financial year as outlined in section 51, which must include—			
(a) details of the financial performance of the Fund, as audited by the Auditor- General, including evidence of the proper and diligent implementation of the Public Finance Management Act;			
(b) details of performance of the Fund in relation to ensuring access to quality health care services in line with the health care needs of the population;			
(c) the number of accredited and approved health care providers; and	It should be accredited and/or contracted health care service providers, health establishments and suppliers. Terminology must be consistent.		the number of accredited and approved, contracted health care service providers, health establishments and suppliers; and
(d) the health status of the population based on such requirements as may be prescribed.	The metrics must be prescribed.		the health status of the population in accordance

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
			with the metrics 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.	.		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 <u>quarterly</u> 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.			
Staff at executive management level			
22. The Chief Executive Officer may not appoint or dismiss members of staff at executive management level without the prior written approval of the Board.			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Chapter 6			
COMMITTEES ESTABLISHED BY BOARD			
Committees of Board			
23. (1) The Board may establish a committee and, subject to such conditions as it may impose, delegate or assign any of its powers or duties to a committee so established.			
(2) Each committee established in terms of subsection (1) must have at least one Board member appointed in term of section 13(1) as a member of that committee.	As per comments provided in Section 24 (4), due to governance concern, it is not recommended that Board members be able to serve on Committee's.		Remove Section 23 (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.	This should be part of Committee Charters. Provision should be made that all Committees should be appointed and function in terms of Committee Charters approved by the Board. The items that must be included in the Charter must be specified e.g. appointment, mandate, powers and functions, remuneration. The Board may		Committees of the Board as established in subsection (1) must meet <u>quarterly</u> per year in order to report to the meeting of the full Board and may convene special meetings to discuss urgent matters when necessary.

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	delegate to the Committee, but not abdicate its responsibility.		
(4) The Board may dissolve or reconstitute a committee on good cause shown.			
Technical committees	This section should be combined with section 23. Its technical committee remains a committee appointed by the Board.		
24. (1) (a) The Board may establish such number of technical committees as may be necessary to achieve the purpose of this Act.			
(b) The provisions of section 29 apply to paragraph (a) with the changes required by the context.			
(2) A committee established in terms of subsection (1)(a) must perform its functions impartially and without fear, favour or prejudice.			
(3) A person appointed as a member of such a committee must—			
(a) be a fit and proper person;			
(b) have appropriate expertise or experience; and			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(c) have the ability to perform effectively as a member of that committee.			
(4) A member of such a committee must not—	Members of Committees should not be employees of the state. Members of the Board should not be able to serve on any Committees.		Add the following sub-clauses; Members of Committees should not be employees of the state. Members of the Board should not be able to serve on any Committees.
(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	Conflict of interest provisions must apply to all Committee members.		
(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	It is not acceptable from a governance point of view that the Minister may establish committees with independent powers that are imposed on the Board of the Fund.	The governance framework must comply with King Code of Corporate Governance (King IV).	ADVISORY COMMITTEES ESTABLISHED BY THE BOARD

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	All committees must function under the auspices of the Board.		
Benefits Advisory Committee			
25. (1) The Minister must, after consultation with the Board and by notice in the Gazette, establish a committee to be known as the Benefits Advisory Committee as one of the advisory committees of the Fund.	It is not acceptable from a governance point of view that the Minister may establish committees with independent powers that are imposed on the Board of the Fund. All committees must function under the auspices of the Board. The size of the committees must be specified as well as their mandates. All these committees must function in terms of Charters. They must make recommendations to the Board. The final decision-making power must vest in the Board. The Board is financially accountable. It must be able to determine what it can		The Board must establish a committee to be known as the Benefits Advisory Committee as one of the advisory committees of the Fund. Notice should be given by use of the Gazette,

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	afford in terms of benefits with reference to its budgets. It cannot be imposed on the Board what it must fund by an outside entity.		
(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.	These committees will play critical roles and contribute to the ultimate success of the Fund. It is hence proposed that a transparent selection process be followed by the Board to ensure that persons with appropriate experience, skills and expertise are included on these committees. Inclusion of member appointments with expertise in Medical Devices and IVD's. The size of the committees must be specifiedThe Minister should not be represented on any committee's in provision for good governance. It must be a Committee of skilled and experienced persons who can appropriately recommend benefits.	This individual must have biomedical engineering expertise and specific experience with Medical Devices and IVD'S	The membership of the Benefits Advisory Committee, appointed by the Board, must consist of persons with technical expertise in medicine, Medical Devices and IVD's. public health, health economics, epidemiology, and the rights of patients.

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(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.	This clause is not aligned with the requirements for Committee members in Chapter 6, Section 23.	Requirements for Committee members need to be aligned.	Align clause with requirements in Chapter 6, Section 23.
(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	All benefits finally approved by the Board and all treatment guidelines must be published in the Government Gazette.	Treatment guidelines and protocols must be evidence-based. Their development requires the input of experts in the various fields.	

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(c) in consultation with the Minister and the Board, the health service benefits provided by the Fund.	The Committee can only recommend to the Board.		Make recommendations regarding health service benefits provided by the Fund to the Board.
(6) The Minister must appoint the chairperson from amongst the members of the Committee.	The Minister should not have any involvement in the appointment of the Committee chair. In terms of good governance practices the Committee should elect a chairperson from its number at its first meeting.	The appointment by the minister could call into question the appropriateness of the appointment.	In accordance with good corporate governance, we recommend the following change *The Committee 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.			
Health Care Benefits Pricing Committee			
26. (1) The Minister must, after consultation with the Board and by notice in the Gazette, establish a Health Care Benefits Pricing Committee as one of the advisory committees of the Fund, consisting of not less than 16 and not more than 24 members.	It is not acceptable from a governance point of view that the Minister may establish committees with independent powers that are imposed on the Board of the Fund.		(1) The Board must, 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

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	All committees must function under the auspices of the Board.		and not more than 24 members.
(2) The Health Care Benefits Pricing Committee consists of persons with expertise in~~——5~~ actuarial science, medicines, epidemiology, health management, health economics, health financing, labour and rights of patients, and one member must represent the Minister.	Include appointments of expertise in Medical Devices and IVD's There is no need for the Minister to be represented. It must be a Committee of skilled and experienced persons who can recommend prices.	This includes all other experts beside the expertise in MDs and IVDs	The Health Care Benefits Pricing Committee consists of persons with expertise in actuarial science, medicines, Medical Devices and IVD's epidemiology, health management, health economics, health financing, labour and rights of patients,
(3) The Committee must recommend the prices of health service benefits to the Fund.			
(4) The Minister must appoint the chairperson from amongst the members of the ~~10~~ Committee.	The Minister should not have any involvement in the appointment of the Committee chair. In terms of good governance practices the Committee should elect a chairperson from its number at its first meeting.	The appointment by the minister could call into question the appropriateness of the appointment.	In accordance with good corporate governance, we recommend the following change *The Committee must appoint a Chairperson from amongst it's members this appointment should take place at the first meeting of the Committee.*

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Stakeholder Advisory Committee			
27. The Minister must, after consultation with the Board and by notice in the Gazette, appoint a Stakeholder Advisory Committee comprised of representatives from the statutory health professions councils, health public entities, organised labour, civil 15 society organisations, associations of health professionals and providers as well as patient advocacy groups in such a manner as may be prescribed.	It is not acceptable from a governance point of view that the Minister may establish committees with independent powers that are imposed on the Board of the Fund. All committees must function under the auspices of the Board. Please clarify the mandate of the Stakeholder Advisory Committee There is no provision for suppliers of health goods to be on this committee. There is no definition of a provider.	Need to make provision for suppliers to be considered as they have extensive industry knowledge, and this will provide for positive engagement. Unclear as to the who would be incorporated as a 'provider' within this context.	Include the mandate of the committee in this section The Board must 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 15 society organisations, associations of health professionals and providers, suppliers as well as patient advocacy groups in such a manner as may be prescribed. Add a definition of a 'provider'
Disclosure of interests			
28. A member of a committee established by the Minister in terms of this Act who has a personal or financial interest in	It is not acceptable from a governance point of view that		A member of a committee established by the Board in

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
any matter on which such committee gives advice, must disclose that interest when that matter is discussed and be recused during the discussion.	The Minister may establish committees with independent powers that are imposed on the Board of the Fund. All committees must function under the auspices of the Board. Certain interest would preclude a person from participating in the Committee. Align with the provisions related to conflicts of interests.		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.
Procedures and remuneration			
29. When establishing a committee under this Chapter, the Minister must determine by notice in the Gazette—	It is not acceptable from a governance point of view that the Minister may establish committees with independent powers that are imposed on the Board of the Fund. All committees must function under the auspices of the Board.		When establishing a committee under this Chapter, the Board must determine by notice in the Gazette—

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(a) its composition, functions and working procedures;			
(b) in consultation with the Minister of Finance, the terms, conditions, remuneration and allowances applicable to its members; and			
(c) any incidental matter relating to the committee.			
Vacation of office	Should be in Committee Charter		
30. A member of a committee established in terms of this Act ceases to be a member if—	There must also be disqualification criteria and provision made for conflicts of interest. Provide also for deceased members.		Include a clause which reflects the disqualification criteria, as well as a provision for conflict of interest. Provision needs to be made for deceased members.
(a) that person resigns from that committee;			
(b) the Minister terminates that person's membership for adequate reason; or	Board's responsibility		the Board terminates that person's membership for adequate reason; or
(c) the term for which the member was appointed has expired and the ~~35~~ membership has not been renewed.			
Chapter 8			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
GENERAL PROVISIONS APPLICABLE TO OPERATION OF FUND			
Role of Minister			
31. (1) Without derogating from any responsibilities and powers conferred on him or her by the Constitution, the National Health Act, this Act or any other applicable law, the Minister is responsible for—	The involvement of the Minister of Health on all levels of the NHI Fund is not supported.	The granting of extensive powers to the Minister has the effect of making key decisions subject to arbitrary political decision-making. The governance of State-owned enterprises is a case in point where effective management of these entities are too often frustrated by political interference. Legal requirements and clinical elements of the system must be rational, objective and transparent and not left to political intervention.	
(a) governance and stewardship of the national health system; and	Requires committee engagement & approvals for more transparency and better governance		

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(b) governance and stewardship of the Fund in terms of the provisions of this Act.	Requires committee engagement & approvals for more transparency and better governance . The Fund is a Schedule 3A entity. The Minister should be mindful that responsibility for governance and stewardship should lie with the Board.		In conjunction with the Board, for the governance and stewardship of the Fund in terms of the provisions of this Act.
(2) The Minister must clearly delineate in appropriate legislation the respective roles and responsibilities of the Fund and the national and provincial Departments, taking into consideration the Constitution, this Act and the National Health Act, in order to prevent duplication of services and the wasting of resources and to ensure the equitable provision and financing of health services.			
Role of Department			
32. (1) The functions of the Department are outlined in the National Health Act and the Constitution, and include—			The functions of the Department are outlined in the National Health Act and the Constitution.
(a) issuing and promoting guidelines for norms and standards related to health matters;			Delete this subsection, as this is already defined within the National Health Act and/or the Constitution.

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(b) implementing human resources planning, development, production and management;			Delete this subsection, as this is already defined within the National Health Act and/or the Constitution.
(c) co-ordinating health care services rendered by the Department with the health care services rendered by provinces, districts and municipalities, as well as providing such additional health services as may be necessary to establish an integrated and comprehensive national health system;	This is an amendment to the current functions as stipulated in the National Health Act. The relevant section in the National Health Act must be amended. This amendment is not aligned with the proposed amendments of the relevant sections of the National Health Act as set out in the Schedule to the Bill. All proposed amendments must be included in the National Health Amendment Bill.		Delete this subsection, as this is already defined within the National Health Act and/or the Constitution
(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			Delete this subsection, as this is already defined within the National Health Act and/or the Constitution
(e) integrating the annual health plans of the Department and the provincial and district health departments and submitting the integrated health plans to the National Health Council.			Delete this subsection, as this is already defined within the National Health Act and/or the Constitution
(2) Subject to the transitional provisions provided for in section 57, the Minister may introduce in Parliament proposed	To be reviewed		

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
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—	The Minister may introduce amendments to the NHA. It does not need to be provided for in this Bill. There are already amendments proposed to the NHA in the Schedule to this Bill.		It is requested that a National Health Amendment Bill be published, which contains all the proposed amendments and to which comprehensive comments can be submitted.
(a) delegate to provinces as management agents, for the purposes of provision of health care services, and in those cases the Fund must contract with sections within the province such as provincial tertiary, regional and emergency medical services;			
(b) designate provincial tertiary and regional hospitals or groups of hospitals as autonomous legal entities accountable to the Minister through regulation; and			
(c) establish District Health Management Offices as government components to manage personal and non-personal health care services.			
(3) Without derogating from the Constitution or any other law, the functions of a provincial Department must be amended to comply with the purpose and provisions of this Act, subject to the provisions of section 57.			
Role of medical schemes			
33. Once National Health Insurance has been fully implemented as determined by the Minister through regulations in the Gazette, medical schemes may only offer	SAMED supports a dispensation in terms of which persons are able to choose how and where they	In a free market economy such restrictions are not appropriate. In addition,	Amend section 33

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
complementary cover to services not reimbursable by the Fund.	spend their private money. Furthermore, national health systems across the world exist alongside private health systems. Hence any restriction on the cover that medical schemes or other private health insurance schemes may offer is not supported. In a free market economy such restrictions are not appropriate. The rationale for imposing restrictions on the ability of medical schemes to offer parallel cover the NHI Fund is not clear. It should be noted that the opposition to the proposed role for medical schemes should not be construed as opposition to the principles of universal coverage. More detail on what services would fall under complementary cover compared to services provided under NHI is needed. This links to defining complementary health care which will form part of private cover.	any restriction on the ability of medical schemes to function as funders of comprehensive services, will result in the closure of schemes and supporting service providers with an anticipated negative impact on the economy as it will result in many retrenchments and the ceasing of other economic activities that contribute to the economy of South Africa. This might result in a closure of many of these businesses or a withdrawal from South Africa. Should it be persisted with this position of restricting the ability of medical schemes to offer comprehensive cover for medical services, it is likely to be subjected to constitutional scrutiny.	
National Health Information System			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
34. (1) The Fund must contribute to the development and maintenance of the national health information system as contemplated in section 74 of the National Health Act through the Information Platform established in terms of section 40.	Data is critical to the Fund's operation; therefore, it should do much more than merely contribute to the development and maintenance of the system.	Currently this data system is under the remit of the National Department of Health therefore alignment of functions is required. An integrated sophisticated data system is required. The fund should ring-fence budget for this purpose and appoint a highly professional team to ensure its upkeep	.
(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.	'Health workers' to be removed from this subsection. Consistency in use of terminology must occur.	The relevant persons and health establishments are subject to the NHA and must comply with its provisions (as well as the	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

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		provisions in other legislation).	records and the protection of health records.
Purchasing of health care services	Any reimbursement strategy must consider the total cost of providing a particular service, e.g. consumables and equipment required to provide a service. In the private sector health service providers and health establishments are responsible for all their overheads e.g. rental of rooms, purchasing of equipment, hiring of staff, obtaining professional indemnity cover, etc. Reimbursement must be sufficient to cover these overheads. Furthermore, it will have a direct impact on the constitutional rights of service providers and users, which need to be understood and respected.		
35. (1) The Fund must actively and strategically purchase health care services on behalf of users in accordance with need.	Uncertain as to what is considered to be 'strategic purchasing'	More detail on the strategic purchasing model is required, and what control mechanisms	The Fund must actively and strategically purchase health care services on behalf of users in accordance with need, and in alignment with

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	It is assumed that 'need' refers to the need by users. On what basis will 'need' be determined?	will be in place to manage procurement	requirements as per the PFMA.
(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.	The position of private hospitals and private medical specialists as well as other practitioners not part of CUPs must be clarified. No timeline has been indicated for fund transfers in regulations and as prescribed.	Clarity is required as to the conditions this can be applied to, and requires timeous notification and deadlines. Fund transfer timelines should be provided as prescribed in regulation under the PFMA.	The Fund must transfer funds directly to accredited, approved and contracted central, provincial, regional, specialised and district hospitals based on a global budget or Diagnosis Related Groups in alignment with the requirements of the PFMA.
(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.	How will funds be shared at CUP level amongst the various service providers?		The Fund must transfer the agreed reimbursement for primary health care services directly to contracted 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.	It is suggested that the remuneration mechanisms should not be predetermined but left to the Pricing Committee and Board to	Clarification is required by industry as to whether this would include fees payable to suppliers, or just to 'service providers'.	. Include a definition of 'capped case-based fee' and what is included therein.

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	determine the most appropriate mechanisms.		
(b) Public ambulance services must be reimbursed through the provincial equitable allocation.	This provision is in conflict with the provisions of subsection (4)(a).		Delete subsection (4)(b)
Role of District Health Management Office			
36. A District Health Management Office established as a national government component in terms of section 31A of the National Health Act must manage, facilitate, support and coordinate the provision of primary health care services for personal health care services and non-personal health services at district level in compliance with national policy guidelines and relevant law.	The functions and duties of this Office is included in amendments to the National Health Act included in the Schedule to the Bill. This section is not aligned with these proposed amendments and is superfluous. These sections relate to an area of strategic importance as this is where the current public sector primary health care system starts to engage with GP's in the private sector. SAMED strongly encourages collaborative engagement on this	This process requires wide consultation with the private sector and relevant stakeholders. The management teams appointed at this interface need to be suitably qualified for this critical role.	
Contracting Unit for Primary Health Care	CUPs' functions and their establishment are dealt with under the proposed amendments to the National		

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	Health Act included in the Schedule to the Bill. Section 37 is not aligned with these proposed amendments. It is superfluous and not appropriate to include these provisions in the Bill.		
37. (1) A Contracting Unit for Primary Health Care established in terms of section 31B of the National Health Act—			
(a) manages the provision of primary health care services, such as prevention,promotion, curative, rehabilitative ambulatory, home-based care and community care in a demarcated geographical area; and			
(b) is the preferred organisational unit with which the Fund contracts for the provision of primary health care services within a specified geographical area.			is the preferred organisational unit with which the Fund contracts for the provision of primary health care services within a specified geographical area. <u>The Fund is not precluded from contracting directly with primary health care service providers based on need.</u>
(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			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
organised in horizontal networks within a specified geographical sub-district area, and must assist the Fund to—			
(a) identify health care service needs in terms of the demographic and epidemiological profile of a particular sub-district;			
(b) identify accredited public and private health care service providers at primary care facilities;			
(c) manage contracts entered into with accredited health care service providers, health establishments and suppliers in the relevant sub-district in the prescribed manner and subject to the prescribed conditions;			
(d) monitor the disbursement of funds to health care service providers, health establishments and suppliers within the sub-district;	Although goods will be procured centrally, funds will then be paid via the Contracting units for Primary Health Care per geographical area. We need better understanding of the flow of funds. Will CUPS be responsible for the payment or merely have a monitoring function?	This section needs to be expanded to deal with suppliers of goods, as well as the inclusion of PFMA and any other relevant procurement legislation. The Bill refers to a centralized procurement system, yet Section 35 mentions disbursement of funds at various levels.	SAMED recommends that specific provision be made for payment of suppliers aligned with PFMA.
(e) access information on the disease profile in a particular sub-district that would inform the design of the health care service benefits for that sub-district;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(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;	The cost of this additional transport must be quantified, and resources need to be provided	The cost for users to access various levels of care outside of their geographical location, may be prohibitive for many.	
(h) facilitate the integration of public and private health care services within the sub-district; and			
(i) resolve complaints from users in the sub-district in relation to the delivery of health care services.			
Office of Health Products Procurement			
38. (1) The Board, in consultation with the Minister, must establish an Office of Health Products Procurement which sets parameters for the public procurement of health related products.	It needs to be clarified whether the current Office of the Chief Procurement Officer will be absorbed into this office and how the draft Procurement Bill, which has been submitted to Cabinet will align with these provisions. There is no need for the Board to consult with the Minister to discharge a function of the Fund, i.e.		The Board, after consultation with the Minister, must establish an Office of Health Products Procurement which sets parameters for the procurement of health goods and health related products.

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
	procurement. The Board is responsible.		
(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;	More detail on this selection process must be provided These sections relate to an area of strategic importance as the successful procurement of health-related products is of critical importance to the success of Universal Health Care. SAMED strongly encourages collaborative engagement on this.	This process requires wide consultation with relevant stakeholders. The management teams appointed at this interface need to be suitably qualified for this critical role.	Determine the selection of health goods and health related products to be procured;

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(b) Develop a national health products list;	Clarification is required as to how, when and against what criteria this list will be developed. These sections relate to an area of strategic importance as the successful procurement of health-related products is of critical importance to the success of Universal Health Care. SAMED strongly encourages collaborative engagement on this.	This process requires wide consultation with the relevant stakeholders as the impact of what is included/excluded in this list could be significant. The management teams appointed at this interface need to be suitably qualified for this critical role.	
(c) coordinate the supply chain management process and price negotiations for health related products contained in the list mentioned in paragraph (b);			
(d) facilitate the cost effective, equitable and appropriate public procurement of health related products on behalf of users;	Would product choice come down to end-user preference?		facilitate the cost effective and appropriate procurement of health related products and health goods on behalf of users;
(e) support the processes of ordering and distribution of health related products nationally, and at the district level with the assistance of the District Health Management Office;			

Clause / section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(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;			establish mechanisms to monitor and evaluate the risks inherent in the procurement process;
(h) facilitate the procurement of high cost devices and equipment; and	What will qualify as a 'high cost device'? Will high cost devices not be included on the product list as per section 3 (b)? ?	The costs of procuring capital equipment for healthcare providers can be significant and consideration needs to be taken into account for the maintenance of equipment.	

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(i) advise the Board on any matter pertinent to the procurement of health related products.			Advise the Board on any matter pertinent to the procurement of health goods and 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.	Comprehensive medicines, equipment and diagnostic lists must be developed against clear evidence-based parameters. It is advisable that an HTA process is a key contributor to these lists. It needs to be included under the functions of this office that it has to develop and maintain a formulary subject to the changes proposed above and that it is responsible for the regular review of this list as contemplated in subsection (5), including the development in new technology.	A comprehensive, evidence-based product listing is imperative to the success of the NHI. Not providing for a variety of suppliers on an item, could result in detrimental supply issues, and ultimately affect patient treatments.	The Office of Health Products Procurement must support the Benefits Advisory Committee in the development and maintenance of the Formulary. SAMED recommends that the formulary should include multiple suppliers for supply against a specific item

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
	Lack of clarity of whether a variety of suppliers will be included within the formulary for supply of an item. This is especially important due to the exclusion of the Competition Act. There is no need for the Minister to approve the list. This is a function of the Board. The involvement of the National Health Council in this is not required.		
(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.			The Office of Health Products Procurement must support the review of the Formulary annually, or more regularly if required, to take into account changes in the burden of disease, product availability, technological developments, price changes and disease management for approval by the relevant committee, and the Board.

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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.	Align with subsection (3)(e) above.		
(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).			
Accreditation of service providers			
39. (1) 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.			
(2) In order to be accredited by the Fund, a health care service provider or health establishment, as the case may be, must—			In order to be accredited by the Fund, a health care service provider or health establishment must—

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(a) be in possession of and produce proof of certification by the Office of Health Standards Compliance and proof of registration by a recognised statutory health professional council, as the case may be; and			
(b) meet the needs of users and ensure service provider compliance with prescribed specific performance criteria, including the—			
(i) provision of the minimum required range of personal health care services specified by the Minister in consultation with the Fund and published in the Gazette from time to time as required;	This will be agreed in contracts between the Fund and relevant service providers / establishments. The Minister should not be involved in this process. Publication of a 'required range of services' will result in inflexibility in contracting. Contracts must be customised according to the service providers' / health establishments' nature, location and structure.		provision of the required range of personal health care services specified in consultation with the Fund and published in the Gazette from time to time as required;

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(iii) adherence to treatment protocols and guidelines, including prescribing medicines and procuring health products from the Formulary;	Terminology must be consistently used. Other provisions of the Bill only refer to 'treatment guidelines.		adherence to treatment guidelines, including prescribing medicines and procuring health products from the Formulary;
(iv) adherence to health care referral pathways;	Only patients can adhere to referral pathways. However, it could be expected of service providers and establishments to refer according to stipulated referral pathways.		Referring patients in accordance with stipulated 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	Align the information requirements. Refer also to subsection (5).		submission of information as prescribed to the national health information system to ensure portability and continuity of health care services in the Republic and performance monitoring and evaluation; and
(vi) adherence to the national pricing regimen for services delivered.	Alignment of terminology is required. 'Pricing Regimen' has not been defined. Provision should be made for adherence to contracted prices.		adherence to the agreed prices for services delivered.

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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—	Provision needs to be made for medical specialist and other practitioners and allied professionals not operating within the frameworks given below.		The Fund must conclude a legally binding contract with a health establishment certified by the Office of Health Standards Compliance and with any other accredited and approved health care service provider that satisfies the requirements listed in subsection (2) to provide— Add in a subsection to include the services rendered by medical specialist and other practitioners and allied professionals operating within alternative frameworks.
(a) primary health care services through Contracting Units for Primary Health Care;	Will the contract be with the CUP or the relevant primary health care service provider?	It is recommended that the Fund should also have the ability to contract directly with primary care services providers, other than through CUPs.	
(b) emergency medical services; and			
(c) hospital services.			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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.	Would there be a prescribed minimum or maximum volume linked to duration contained in the contract? What does 'volume" entail? Will a contracted service provider be expected to accept a certain number of patients? Can the provider refuse to accept any more / other patients when the limit has been reached?		
(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 ~~10~~ the Health Patient Registration System, including—	Align Health Patient Registration System with the national health information system.	Any information must be easy to provide. It must be done electronically in standardised formats, which are easy to provide for all service providers and establishments.	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 of user data on ~~10~~ the National Health Information System, including—
(a) national identity number or permit and visa details issued by the Department of Home Affairs, as the case may be;			
(b) diagnosis and procedure codes using the prescribed coding systems;			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(c) details of treatment administered including medicines dispensed and equipment used;			
(d) diagnostic tests ordered;			
(e) length of stay of an inpatient in a hospital facility;	Terminology must be clarified. If 'health establishment' is used to depict a facility like a hospital, that is the term that should be used.		length of stay of an inpatient in a health establishment.
(f) facility to which a user is referred if relevant;	A user could also be referred to another practitioner.		Facility or practitioner 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.	Information to be submitted must be specified in the Government Gazette	Information required should not change frequently as it has resource and system implications for service providers and establishments. This should be aligned with relevant legislation.	

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(6) The performance of an accredited health care service provider or health establishment must be monitored and evaluated in accordance with this Act and appropriate sanctions must be applied where there is deviation from contractual obligations as per the law.			
(7) The Fund must renew the accreditation of service providers every five years on the basis of compliance with the accreditation criteria as reflected in subsection (2).			
(8) The Fund may withdraw or refuse to renew the accreditation of a health care service provider or health establishment if it is proven that the health care service provider or health establishment, as the case may be—			
(a) has failed or is unable to deliver the required comprehensive health care service benefits to users who are entitled to such benefits;	'Comprehensive' should be removed to align it with other provisions of the Bill and to provide for flexibility in contracting.		has failed or is unable to deliver the required health care service benefits to users who are entitled to such benefits;
(b) is no longer in possession of, or is unable to produce proof of, certification by the Office of Health Standards Compliance and of proof of registration by the relevant statutory health professions council, as the case may be;			

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(c) has failed or is unable to ensure the allocation of the appropriate number and mix of health care professionals to deliver the health care services specified in the Gazette;	Consideration needs to be given to geographical limitations and/or area of specialisation of a specific health establishment.		Amend section (c) to allow for exclusions.
(d) has failed or is unable to adhere to treatment protocols and guidelines, including prescribing medicines and procuring health products from the Formulary;			
(e) has failed or is unable to comply with health care referral pathways;			
(f) for any reason whatsoever, does not submit to the Fund the information contemplated in section 34(3) timeously;	Timeline requirement are needed in order to validate compliance.		
(g) fails to adhere to the national pricing regimen for services delivered;	Refer to the comments above in respect of the national pricing regimen'. It is advisable to refer to contracted prices.		fails to adhere to the contracted prices for services delivered;
(h) intentionally or negligently breaches any substantive terms of a legally binding contract concluded with the Fund;			
(i) fails or is unable to perform as required by the terms of a legally binding contract concluded with the Fund;			

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(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.	What does a 'code of health related ethics or relevant law' refer to?	A clear code of ethics needs to be applied to all participants included in the fund.	
(9) If the Fund withdraws the accreditation of a health care service provider or health establishment, or refuses to renew the accreditation of a health care service provider or health establishment, the Fund must—			
(a) provide a health care service provider or health establishment with notice of the decision;	Written reasons must also be provided as contemplated in the Promotion of Administrative Justice Act.		provide a health care service provider or health establishment with written notice of the decision as well as reasons for the decision;
(b) provide a health care service provider or health establishment with a reasonable opportunity to make representations in respect of such a decision;			
(c) consider the representations made in respect of paragraph (b); and			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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.	This provision can be combined with subsection 9a)		provide adequate written reasons 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.			
(11) The Fund may issue directives relating to the listing and publication of accredited health care service providers and health establishments.			
Information platform of Fund			
40. (1) The Fund must establish an information platform to enable it to make informed decisions on population health needs assessment, financing, purchasing, patient registration, service provider contracting and reimbursement, utilisation patterns, performance management, setting the parameters for the procurement of health goods, and fraud and risk management.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(2) Health care service providers and health establishments must submit such ~~15~~ 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).	This subsection must be aligned with the prescribed information submission requirements set out above.		
(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;			
(c) monitor adherence to standard treatment guidelines, including prescribing from the Formulary;			
(d) monitor the appropriateness and effectiveness of referral networks prescribed by health care service providers and health establishments;			

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(e) provide an overall assessment of the performance of health care service providers, health establishments and suppliers; and	There is no requirement for suppliers to submit information. The reference to suppliers must be deleted.		provide an overall assessment of the performance of health care service providers and health establishments; 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—	Caution against the provision of personal information by third parties such as private medical schemes and must be within the provisions of POPI. These provisions already appear in the National Health Act. There is no reason to include them also in this Bill. Refer also to section 34(3). Provisions must be aligned.		Information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment is confidential and no third party may disclose information contemplated in subsection (2), other than as provided for in the National Health Act and the Protection of Personal Information Act, unless - .
(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;			

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(c) the information is required by an accredited health care service provider, health establishment, supplier or researchers for the lawful purpose of improving health care practices and policy, but not for commercial purposes;			
(d) the information is utilised by the Fund for any other lawful purpose related to the efficient and effective functioning of the Fund;			
(e) a court order or any law requires such disclosure; or			
(f) failure to disclosure the information represents a serious threat to public health.			
(5) The information architecture must include a fraud and risk management mechanism.			
(6) In order to fulfil the requirements for dissemination of information and the keeping of records, the information platform must facilitate—			
(a) the implementation of the objects and the effective management of the Fund; and			
(b) portability and continuity of health care services available to users subject to the provisions of this Act.			
Payment of health care service providers	.		

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
41. (1) The Fund, in consultation with the Minister, must determine the nature of provider payment mechanisms and adopt additional mechanisms.	Refer to sections 10 and 11 related to the functions and powers of the Fund and the comment made at these sections, The Board must determine the provider payment mechanisms. It is the governing and as such accountable body. What additional mechanisms are envisaged?		The Fund 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.	No information is provided in the bill in regards to the accreditation of suppliers. Service providers, establishments and suppliers cannot be reimbursed unless they are contracted. They cannot be contracted unless they are accredited.	Medical devices and IVD accreditation should be aligned with SAHPRA and international harmonisation	Include accreditation requirements for all categories of suppliers.
(3) (a) An accredited primary health care service provider must be contracted and remunerated by a Contracting Unit for Primary Health Care.	The contracting function is that of the Fund. This cannot also be the function of CUPs.		

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
	The proposed amendments to the NHA does not provide for CUPs to have contracting functions. This section must be aligned with section 35. Refer also to the amendments proposed to the National Health Act in the Schedule. It also provides for the District Health Management Offices to provide certain services on behalf of CUPs. The provisions of the legislation must be aligned. Provision must be made for the Fund to contract and reimburse primary care providers.		
(b) In the case of specialist and hospital services, payments must be all-inclusive and based on the performance of the health care service provider, health establishment or supplier of health goods, as the case may be.	This provision is not clear and not aligned with the other related provisions in the Bill.	The payment of suppliers must be specifically clarified	

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
	What does “all-inclusive” mean? Who will be paid? The service provider and the establishment and the supplier?	Definition of ‘all-inclusive’ is required.	
(c) Emergency medical services must be reimbursed on a capped case-based fee basis with adjustments made for case severity, where necessary.	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 Refer to the comments made at section 35(4) above.		
(4) Without limiting the powers of the Minister to make regulations in terms of section 55, the Minister may make regulations to—	It is important to include all stakeholders in a consultative process All Regulations should be combined in one section. It is proposed that all Regulations should be dealt with on terms of section 55.		
(a) provide that payments may be made on condition that there has been compliance with quality standards of care or the achievement of specified levels of performance;			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(b) determine mechanisms for the payment of an individual health worker and health care provider; and	Remove 'health worker'. The payment of individual health care service providers is supported. However, the provisions of the Bill as pointed out above must also provide for this.		determine mechanisms for the payment of the health care provider; and
(c) provide that the whole or any part of a payment is subject to the conditions outlined in a contract and that payments must only be effected by the Fund if the conditions have been met.			
(5) For the purposes of subsection (4), ''health worker'' and ''health care provider'' have the meanings ascribed to them in section 1 of the National Health Act.	All definitions should be included in section 1. To eliminate confusion the terms 'health care provider' and 'health care service provider' must not both be used.		Delete subsection (5) and include the relevant definitions in Section 1 of the NHI bill.
Chapter 9			
COMPLAINTS AND APPEALS			
Complaints			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
42. (1) An affected natural or juristic person, namely a user, health care service provider, health establishment or supplier, may furnish a complaint with the Fund in terms of the procedures determined by the Fund in consultation with the Minister, and the Fund must deal with such complaints in a timeous manner and in terms of the law.	~~Provision should also be made for suppliers to lodge complaints or any person affected. Hence it is proposed that the wording be broadened to accommodate other possible scenarios~~. The complaints process and timeframes must be stated in the Bill in the interest of clarity and transparency.		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. The Fund must deal with such complaints in. accordance with the prescribed mechanisms and timeframes.
(2) The Investigating Unit established by the Chief Executive Officer in terms of section 20(2)(e) must launch an investigation to establish the facts of the incident reported and must make recommendations to the Chief Executive Officer as to the way in which the matter may be resolved within 30 days of receipt of the complaint.	Provision should be made for proper processes to be followed. For example, if there is a complaint against a particular service provider or supplier, the rules of natural justice must be applied, and all parties must be provided with an opportunity to respond to these complaints.	Lack of formal processes could contribute to a lack of procedural governance. This could allow for any complaints to not be given the required due diligence in evaluation.	

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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;	It is assumed that a complaint will relate to a health care service provider. Provision should be made for any person or entity against whom a complaint is lodged to be able to respond.	Complaints may refer to other entities with the NHI framework.	Provide the entity against whom the complaint was lodged with a notice of the decision to provide the respondent with a reasonable opportunity to make representations in respect of such a decision;
(b) consider the representations made in respect of paragraph (a); and			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(c) 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.	The complaint will not necessarily be in respect of the withdrawal or refusal to renew accreditation.	Provision should be made for the procedure to deal with any type of complaint related to the functions and powers of the Fund or any duty discharged or service performed in terms of the Bill.	provide adequate reason for the outcome of the decision as it determined to the entity affected, as the case may be.
Lodging of appeals			
43. A natural or juristic person, namely a user, health care service provider, health establishment or supplier aggrieved by a decision of the Fund delivered in terms of section 42 may, within a period of 60 days after receipt of written notification of the decision, appeal against such decision to the Appeal Tribunal.	The wording must be broader to cover all relevant persons. It is suggested that only the persons involved in the complaint should be able to appeal a decision,		The complainant or the respondent who is 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.
Appeal Tribunal			
44. (1) An Appeal Tribunal is hereby established, consisting of five persons appointed by the Minister:	Provision must be made for a transparent nomination and appointment process.	Tribunal should be independent to allow for transparency and corrective actions to be taken.	Assign the appointment of the Tribunal responsibility to Board in accordance with 42 (1)

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
	Invitations for nominations should be published in the Government Gazette as well as the final appointment of the relevant members. Tribunal members should NOT be appointed by the Minister to ensure transparency and limit concerns of political interference.	Align with 42(1)	An Appeal Tribunal is hereby established, consisting of five persons appointed by the Board, and published in the Gazette:
(a) One member appointed on account of his or her knowledge of the law, who must also be the chairperson of the Board;	It is assumed that this member must be the chairperson of the Tribunal and not the Board.		One member appointed on account of his or her knowledge of the law, who must also be the chairperson of the Appeal Tribunal;
(b) two members appointed on account of their medical knowledge; and	Provision should be made to co-opt other people with relevant expertise depending on the complaint at hand e.g. if it affects the supply of a specific health service product.		

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(c) two members appointed on account of their financial knowledge.			
(2) A member of the Appeal Tribunal appointed by the Minister in subsection (1) must serve as a member for a period of three years, which term is renewable only once.			
(3) A member ceases to be a member if—	There must also be disqualification criteria and provision made for conflicts of interest. Provide also for deceased members.	Include a clause which reflects the disqualification criteria, as well as a provision for conflict of interest. Provision needs to be made for deceased members. Reasons for cession of duties should be publicly announced in the gazette.	
(a) he or she resigns from the Appeal Tribunal;			

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(b) the Minister terminates his or her membership on good cause; or	Specific reasons for their termination of a person's membership must be specified.	Transparency needs to be provided should any membership be terminated by the Minister. Required through public announcement.	
(c) the term for which the member was appointed has expired and has not been renewed or after a second term may not be renewed.			
Powers of Appeal Tribunal			
45. (1) The Appeal Tribunal has the same power as a High Court to—	The parties appearing before the Tribunal should equally have the same rights as they would have in the High Court e.g. legal representation, cross-examinations, etc.		Inclusion of a clause which reflects the rights of all parties appearing before the Tribunal. e.g. legal representation, cross-examinations, etc.
(a) summon witnesses;			
(b) administer an oath or affirmation;			
(c) examine witnesses; and			
(d) call for the discovery of documents and objects.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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.	Can the Appeal Tribunal make any cost orders?	Provide clarity on the abilities of the Appeal Tribunal.	
Secretariat			
46. The Chief Executive Officer of the Board must designate a staff member of the Fund to act as secretary of the Appeal Tribunal and the Fund must keep the minutes and all records of a decision of the Board for a period of at least three years after the decision has been recorded.	Provision must be made for a proper recording of proceedings and management of matters. A single staff member may not be enough. It is suggested that the Appeal Tribunal should have its own staff and infrastructure. The decision referred to is that of the Tribunal and not the Board.	It is proposed that the Appeal Tribunal should have its own staff complement and infrastructure.	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 Tribunal for a period of at least three years after the decision has been recorded.
Procedure and remuneration			
47. (1) The Minister, in consultation with the Minister of Finance and the Fund, must determine the terms, conditions, remuneration and allowances applicable to the members of the Appeal Tribunal.			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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.	Align with section 46 in respect of record-keeping.		Align with section 46 in respect of record-keeping.
(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			
Sources of funding			
48. The revenue sources for the Fund consist of—			
(a) money to which the Fund is entitled in terms of section 49;			
(b) any fines imposed in terms of this Act other than by a court of law;			
(c) any interest or return on investment made by the Fund;			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(d) any money paid erroneously to the Fund which, in the opinion of the Minister, cannot be refunded;	This is not acceptable. Any money erroneously paid to the Fund must be repaid and cannot be a source of funding.		any money paid erroneously to the Fund which, in the opinion of the Minister, will be refunded;
(e) any bequest or donation received by the Fund; and			
(f) any other money to which the Fund may become legally entitled.			
Chief source of income			
49. (1) The Fund is entitled to money appropriated annually by Parliament in order to achieve the purpose of the Act.			
(2) The money referred to in subsection (1) must be—	This must be dealt with in a dedicated financial plan. It is not production to pre-empt sources without clear guidelines.		Delete subsection (2)
(a) appropriated from money collected and in accordance with social solidarity in respect of—	An economic impact assessment is imperative.		

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(i) general tax revenue, including the shifting funds from the provincial equitable share and conditional grants into the Fund;		Over-burdening of the tax base could have severe unintended consequences.	
(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	No need for surcharge on personal income tax	There needs to be a clear funding model which make use of a number of funding channels. There is already a very high personal tax burden on a very small tax base.	
(b) calculated in accordance with the estimates of income and expenditure as contemplated in section 53 of the Public Finance Management Act.	In terms of **section 53**(1) of the **PFMA**, the accounting authority of a public entity		

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
	listed in Schedule 3A or 3C to the **PFMA** must submit a budget of estimated revenue and expenditure for that financial year for approval by the executive authority responsible for that public entity.		
(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.			
Auditing			
50. The Auditor-General must audit the accounts and financial records of the Fund annually as outlined in the Public Audit Act, 2004 (Act No. 25 of 2004).			
Annual reports			
51. (1) As the accounting authority of the Fund, the Board must submit to the Minister and Parliament a report on the activities of the Fund during a financial year as determined by the Public Finance Management Act.	Include a report on Health outcomes as per health market enquiry		

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(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;			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(c) all loans, overdrafts, advances and financial commitments of the Fund;	These must all be included in the powers of the Fund e.g. lending money from a registered financial institution. It is recommended that the financial institution must have a specific international rating to ensure that not any institution is used from a good governance perspective.		
(d) the particulars of all donations and bequests received by the Fund;			
(e) an actuarial valuation report;	It should be done by an independent actuary – not a person involved in any of the structures of the Fund,	Consideration should be given to outsourcing this requirement to allow for integrity of information.	
(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—			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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			
Assignment of duties and delegation of powers			
52. Subject to the Public Finance Management Act—			
(a) the Minister may assign any duty and delegate any power imposed or conferred upon him or her by this Act, except the power to make regulations, to any person in the employ of the Fund; and	The involvement of the Minister of Health on all levels of the NHI Fund is not supported.	The granting of extensive powers to the Minister has the effect of making key decisions subject to arbitrary political decision-making.	Remove Section 52 (a)

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
		The governance of State-owned enterprises is a case in point where effective management of these entities are too often frustrated by political interference. Legal requirements and clinical elements of the system must be rational, objective and transparent and not left to political intervention.	
(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.			
Protection of confidential information			
53. Nothing in this Act affects the provisions in any other legislation or law prohibiting or regulating disclosure of personal or other sensitive information accessible to or in possession of the Fund.			
Offences and penalties			
54. (1) Any person who—			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(a) knowingly submits false information to the Fund or its agents;			
(b) makes a false representation with the intention of obtaining health care service benefits from the Fund to which he or she is not entitled;			
(c) utilises money paid from the Fund for a purpose other than that in respect of which it is paid;			
(d) obtains money or other gratification from the Fund under false pretences; or			
(e) sells or otherwise discloses information owned by the Fund to a third party without the prior knowledge and written consent of the Fund, is guilty of an offence and liable on conviction in a court of law to a fine not exceeding R100 000.00 or imprisonment for a period not exceeding five years or to both a fine and such imprisonment.	It should rather refer to confidential information in the possession of the Fund Fine value of R100 000, and limitation on imprisonment should be reconsidered. Does an absolute value need to be mentioned?	The extent of any fraud committed within this environment should not be limited within the act, but should rather be determined in line with the severity of the offence. Take into consideration that the value of R100 000 now may not have the same value in fore coming years.	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 <u>to a monetary fine, or imprisonment, the value or term of sentence to be determined by the severity of the offence.</u>

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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.	Refer to the comments at section 56. Directives are not supported.		Any person who fails to furnish the Fund or an agent of the Fund with information required by 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.			
Regulations	The Regulations listed in section 44 must be included here.		

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
55. (1) Without derogating from the powers conferred on the Minister by the Constitution and the National Health Act or any other applicable law, the Minister may, after consultation with the Fund and the National Health Council contemplated in section 22 of the National Health Act, make regulations regarding—	Consultation on this is critical, but currently it does not include consideration of all stakeholders	There is a need to be more inclusive to ensure appropriate engagement from all stakeholders. Include Patients and Service providers, as well as appropriately qualified experts in the various sectors as required.	
(a) the legal relationship between the Fund and the various categories of health establishments, health care service providers or suppliers as provided for in the National Health Act;	Reference to suppliers	No definition of suppliers is provided. Provide a definition of 'supplier'	
(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;	Reference to suppliers	No definition of suppliers is provided. Provide a definition of 'supplier'	
(c) 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;			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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;	Reference to suppliers	No definition of suppliers is provided. Provide a definition of 'supplier'	
(e) clinical information and diagnostic and procedure codes to be submitted and used by health care service providers, health establishments or suppliers for reimbursement and reporting purposes to the Fund;			
(f) participation by the fund in the national health information system contemplated in section 74 of the National Health Act, including the Health Patient Registration System referred to in section 39;			
(g) the registration of users of the Fund in terms of section 5;			
(h) the accreditation of health care service providers, health establishments or suppliers;			
(i) the functions and powers of a District Health Management Office;	This is covered in amendments to the National Health Act. Refer to the Schedule.		Delete subsection (i)

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(j) the functions and powers of a Contracting Unit for Primary Health Care Services;	This is covered in amendments to the National Health Act. Refer to the Schedule.		Delete subsection (j)
(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;		Align formulary procedures with comments contained under Section 38.	
(p) investigations to be conducted by the Fund or complaints against the Fund in order to give effect to the provisions of Chapter 8;	The entire complaints procedure should be included in Regulations.	Align complaints procedures in regulations.	

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(q) appeals against decisions of the Fund in order to give effect to the provisions 10 of Chapter 8;	The entire appeals procedure should be included in Regulations.	Align appeals procedures in regulations.	
(r) the manner in which health care service providers, health establishments and suppliers must report to the Fund in respect of health care services purchased by the Fund and the content of such reports;			
(s) the monitoring and evaluation of the performance of the Fund;			
(t) all fees payable by or to the Fund;	What fees are envisaged here?	Clarification is requested as to what fees are identified, and how these will be evaluated and implemented.	
(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;			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(x) the scope and nature of prescribed health care services and programmes and the manner in, and extent to which, they must be funded;	The funding of / payment of services are dealt with in numerous subsections. Everything must be combined and/or aligned,		
(y) the proceedings of the meetings of committees appointed in terms of this Act and a Code of conduct for members of those committees;	Committees should function in accordance with Charters. Refer to the comments above within the relevant committee sections. A Code of Conduct for Committees is a separate item. In terms of good corporate governance, the Board should prepare a Board Charter as well as a Code of Conduct applicable to the Fund and all officers and employees of the Fund.		
(z) the proceedings and other related matters of the Appeal Tribunal;			

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

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(4) Regulations must be tabled in the National Assembly and the National Council of Provinces for a period of one month before being finalised.			
Directives			
56. (1) The Fund may issue directives which must be complied with in the implementation and administration of this Act, and any directives so issued must be published in the Gazette.	It is not acceptable for the Fund to issue directives which are binding. This is a unilateral administrative action and does not provide for any input or comment by interested parties.		Delete section 56 (1)
(2) Any directive issued under this section may be amended or withdrawn in like manner.			Remove section 56 (2)
Transitional arrangements			
57. (1) (a) Despite anything to the contrary in this Act, this Act must be implemented over two phases	The phases mapped out below does not refer to the implementation of the Act.		Delete subsection (1)(a)
(b) National Health Insurance must be gradually phased in using a progressive and programmatic approach based on financial resource availability.	Due to the significant impact of the bill and its extensive ramifications, to the economy,		

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	infrastructure as well as legislation. SAMED recommends that this approach is reconsidered to allow for effective implementation.		
(2) The two phases contemplated in subsection (1)(a) are as follows:			Delete subsection (2)
(a) Phase 1, for a period of five years from 2017 to 2022 which must—	Due to the significant impact of the bill and its extensive ramifications, to the economy, infrastructure as well as legislation. SAMED recommends that this approach is reconsidered to allow for effective implementation.		Recommendation to follow an approach based on milestone achievements.
(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;			

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(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—		Conduct Economic Impact assessment after Phase 1	Recommendation to follow an approach based on milestone achievements.
(i) the continuation of health system strengthening initiatives on an on-going basis;			
(ii) the mobilisation of additional resources where necessary; and			
(iii) the selective contracting of health care services from private providers.			
(3) In Phase 1 the Minister may establish the following interim committees to advise him or her on the implementation of the National Health Insurance:	These committees must have proper and transparent appointment criteria and mandates.		

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	These committees must have proper and transparent appointment criteria and mandates. Everything must be published in the Government Gazette. Transitional provisions deal with the implementation of the system when the Bill has been enacted. The need for interim committees will then no longer exist as the provisions related to the establishment of committees can be put into operation. The power of the Minister to establish these committees must be derived from other legislation, if it is the intention to establish these committee before the finalisation of the Bill.		
(a) The National Tertiary Health Services Committee which must be responsible for developing the framework governing the tertiary services platform in South Africa.			

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(b) The National Governing Body on Training and Development which must, amongst others—			
(i) be responsible for advising the Minister on the vision for health workforce matters, for recommending policy related to health sciences, student education and training, including a human resource for health development plan;			
(ii) be responsible for the determination of the number and placement of (including but not limited to) all categories of interns, community service and registrars;			
(iii) oversee and monitor the implementation of the policy and evaluate its impact; and			
(iv) coordinate and align strategy, policy and financing of health sciences education.			
(c) The Ministerial Advisory Committee on Health Care Benefits for National Health Insurance, which must be a precursor to the Benefits Advisory Committee and which must advise the Minister on a process of priority-setting to inform the decision-making processes of the Fund to determine the benefits to be covered.			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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.	Internationally, HTA is well-entrenched and various models exist, which could be considered by South Africa when designing its own HTA. The costs associated with HTA can be significant. Provision should be made for existing stringent regulatory authorisations and allow for mutual recognition.	SAMED supports and endorses the proposal in the NHI Bill that a Health Technology Assessment (HTA) process is required to ensure the suitable deployment of medical technology in South Africa. SAMED has been actively engaging with stakeholders, most notably the National Department of Health, over many years in an effort to establish an HTA capability for South Africa, which has been lacking in both the public and private health care sectors.	
(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;			

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(b) the structuring of the Contracting Unit for Primary Health Care at district level 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			

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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	The role of national pathology services is not made clear. Vital tests could be offered at a primary healthcare level as well as a secondary and tertiary level. The role of diagnostic screening plays a big role in disease prevention and therapeutic monitoring which are beneficial to patients before it becomes medically necessary.	Consideration of these services should be included when developing requirements for primary care units.	
(h) the initiation of legislative reforms in order to enable the introduction of National Health Insurance, including changes to the—			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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.			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
(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.			
Repeal or amendment of laws			
58. (1) Subject to this section and section 57 dealing with transitional arrangements, the laws mentioned in the second column of the Schedule are hereby repealed or amended to 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.			
Short title and commencement			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed correction if required
59. (1) This Act is called the National Health Insurance Act, 2019, and takes effect on a date fixed by the President by proclamation in the Government Gazette.			
(2) Subject to section 57, different dates may be fixed in respect of the coming into effect of different provisions of this Act.			
SCHEDULE			
REPEAL AND AMENDMENT OF LEGISLATION AFFECTED BY ACT			
(Section 58)			

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No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 101 of 1965	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.".	It is not clear why the Office of Health Products Procurement should be consulted when members of the Pricing Committee are appointed and should prescribe the publication of the single exit price of medicines.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 78 of 1973	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 ex- amination 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.	If medical services procured under this in Act will in future be paid by the NHI Fund, the money that is currently used to pay for these services should be directed to the NHI Fund as a source of income.		

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No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act 56 of 1974	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.			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(a) 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]** ser- vices rendered by him or her <u>which are not covered by the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019,</u> 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:			

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No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		‘‘*(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 be- fore the professional board deter- mines 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.’’.	This change could potentially restrict fees which may be considered as unreasonable from being charged by HCP’s.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 63 of 1982	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 that are not covered by the National Health Insurance Act, 2019—’’.			

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No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 130 of 1993	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 para- graph (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;’’.	If medical services procured under this in Act will in future be paid by the NHI Fund, the money that is currently used to pay for these services should be directed to the NHI Fund as a source of income.		

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No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		The amendment of section 22 by the deletion in subsection (3) of paragraph (a). 3. 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.			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 56 of 1996	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 ser- vices [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.	If medical services procured under this in Act will in future be paid by the NHI Fund, the money that is currently used to pay for these services should be directed to the NHI Fund as a source of income.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(c) In the absence of a tariff for emergency medical treatment the tariffs contemplated in paragraph (a) shall apply] shall be determined, under the National Health Insurance Act, 2019.''; and (b) by the deletion of subsections (5) and (6). 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) 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;''.	Section 17 (4B) (a) Tariffs appropriate to each healthcare setting should be applied, to take into account treatment costs in each setting, including Emergency Medical Treatment costs, the preparation and authorisation of a definitive treatment plan for the victim as part of the acute admission and treatment event, the rehabilitation programme and any subsequent readmissions to an acute care setting, as a result of a causally related injury or accident, in either the private or the public healthcare sector as appropriate, and should involve the appropriate healthcare professionals throughout.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
			Section 17 (4B) (b) In the best interest of the patient, it is critical that Emergency Medical Treatment be commenced as soon as possible following the accident. The following situations could apply : The service was not available from the appropriate service provider or would not be provided without unreasonable delay; Immediate medical or surgical treatment for a prescribed minimum benefit condition was required under circumstances or at locations which reasonably precluded the beneficiary from obtaining such treatment from an appropriate service provider;	Tariffs should be reflective of the wholistic nature and requirement of care, as is deemed appropriate by appropriate health care service providers. Tariffs determined for reimbursement of Emergency Medical care will need to take into account the extent of care required, as determined by the nature of the user's injuries.	Clarification is requested regarding how tariff structures will be applied within these parameters. SAMED suggests that the determination of the tariffs involved are required to give full consideration to the total requirement of care as deemed appropriate by properly qualified and accredited health care service providers.

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		Immediate medical or surgical treatment may be required due to critical required care by a facilty or health care service provider that is not accredited via the NHI system.			No information regarding tariffs is provided within the NHI bill. No indication on how emergency treatments provided by health care service providers is available. Particular concern is given to the tariffs available to unaccredited facilities and health care service providers given the possible requirement of emergency treatment which may be required.

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 89 of 1998	Competition Act, 1998		Exclusion of oversight by the competition commission under the Competition Act could allow for potential unethical/anticompetitive actions by various sectors covered by the NHI bill.	Exclusion of application of the Competition Act in reference to the actions of the NHI could have significant effect on corrupt/ethical practice which could have a negative impact on the patient. Allowing limited exposure/inclusion of the Competition commission within the bill is advisable.	The Competition Act, 1998 (Act No. 89 of 1998), is applicable to any transactions concluded in terms of this Act.

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 111 of 1998	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 ser- vices, based on the principles of universal access to primary health care, in order to allow every in- mate 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].’’.	If medical services procured under this in Act will in future be paid by the NHI Fund, the money that is currently used to pay for these services should be directed to the NHI Fund as a source of income.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 131 of 1998	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 ser- vice that is not covered by the provisions of the National Health Insurance Act, 2019; ***(b)*** granting assistance in defraying expenditure incurred in connection with the rendering of any relevant health care service that is not covered by the provisions of the National Health Insurance Act, 2019; or 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	These amendments make allowance for medical schemes to cover that which is not covered under the NHI – this includes goods procured outside of NHI structures.		‘relevant health service’ not defined in the NHI Act by a person registered in terms of any law, is not well defined 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. Duplicate cover should be permitted by medical schemes, and therefore all proposed amendments to this Act should not occur.

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 131 of 1998	Medical Schemes Act, 1998	1. The amendment of section 1— *(b)* 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 ser- vice that is not covered by the provisions of the National Health Insurance Act, 2019; ***(b)*** granting assistance in defraying expenditure incurred in connection with the rendering of any relevant health care service that is not covered by the provisions of the National Health Insurance Act, 2019; or 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	These amendments make allowance for medical schemes to cover that which is not covered under the NHI – this includes goods procured outside of NHI structures.		‘relevant health service’ not defined in the NHI Act by a person registered in terms of any law, is not well defined 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. Duplicate cover should be permitted by medical schemes, and therefore all proposed amendments to this Act should not occur.

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(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, ill- ness or deficiency; [(d) the giving of advice in relation to, or treatment of, any condition arising out of a pregnancy, including the termination thereof;]			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(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] subject to the provisions of the National Health Insurance Act, 2019, may include complementary and top up and ambulance service, and the sup- ply of accommodation in [an] a 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 per- formed, 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			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(2) 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:	The need for this amendment is unclear. Is the suggestion that section (d) is removed? This could be constitutionally unsound as current law stands.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		‘‘(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.’’.	This specification is in opposition to statements made in the NHI Bill referring to what is denoted in Section 8 (2)? As it currently stands, the bill would take precedence.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 61 of 2003	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 information system;’’; *(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;’’;			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(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 ser- vices 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;			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(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 con- trolling 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:			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		‘‘(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 pre- scribed—’’; *(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:			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		‘‘(n) [control] assist the District Health Management Office in controlling 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 metropolitan or district municipality or District Health Management Office, as the case may be.’’;	These deletions remove these responsibilities from the provincial offices, to become oversight of the district units. This raises concern regarding the level of oversight that the district offices will have in this structure.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(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) 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			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(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 con- templated 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 co- ordinate 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—			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(a) prepare annual strategic medium- term 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 time- frames 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;			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(a) and school health services; (b) provide information on the disease profile in a particular district that would inform the design of the health care service benefits for that district; (c) improve access to health care services at health care facilities and in the community in a particular district; 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 ser- vices but excluding public ambulance services;			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(j) receive and resolve complaints from users in the district in relation to the delivery of health care services; (k) liaise with and report on a monthly basis to the national of- fice 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 ser- vice 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; (l) 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;	This role will fall to that of the District offices to accredit facilities. Concern should be raised regarding the qualifications of those in these units who will be responsible for these evaluations.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(j) 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; (k) develop, procure, use, maintain and protect health technology within the district; and (l) 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 sub- district is effectively and efficiently managed.	(a) Certification is proposed to be a function of the OHSC and accreditation is a function of the NHI Fund. This provision is in conflict with the NHI Bill, which provisions will take precedence. The provisions must be aligned. If accreditation and certification at district level is delegated to the District Health Management Offices, detailed provisions must be included in this regard regarding the criteria, processes, etc.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
			Certification is proposed to be a function of the OHSC and accreditation is a function of the NHI Fund. This provision is in conflict with the NHI Bill, which provisions will take precedence. The provisions must be aligned. If accreditation and certification at district level is delegated to the District Health Management Offices, detailed provisions must be included in this regard regarding the criteria, (a) processes, etc. (b) It is not clear how this aligns with the provisions in the NHI Bill. The provisions must be aligned. (c) These provisions must be aligned with the complaint provisions under the NHI Bill. May a user complain at any level?		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
			Consider the comments in the NHI Bill relating to Investigation Unit. All the provisions must be aligned.		
		Establishment of Contracting Units for Primary Health Care 31B. (1) The District Health Man-agreement 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 pro- vision 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.	(3) The payment mechanisms should not be pre-empted. The NHI bill also contemplates the potential contracting of individual providers. This must also be accommodated.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(2) 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 pro- vide primary health care services. (3) 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. (4) 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 of the following words:	How will suppliers be involved on a primary care level? How ill procurement and their reimbursement work?		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		___ *(a)* "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:			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		‘‘(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 es- sential drugs list and medical and other assistive de- vices list together with the Office of Health Products Procurement; (e) human [resource] resources planning, development and management;’’.			

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 70 of 2008	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;	If medical services procured under this in Act will in future be paid by the NHI Fund, the money that is currently used to pay for these services should be directed to the NHI Fund as a source of income.		

No. and year of Act	Short Title	Extent of repeal or amendment	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
		(a) prescribe remedies for failure to comply with the conditions con- templated in paragraph (a); ***(b)*** establish and maintain a register of all assets bought by service providers with Government funds; and ***(c)*** prescribe conditions for the management and disposal of assets contemplated in para- graph (c). (3) Service providers who pro- cure 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.]			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
MEMORANDUM ON THE OBJECTS OF THE NATIONAL HEALTH INSURANCE BILL, 2019			
1. BACKGROUND			
1. General			
1.1 Cabinet approved the policy for the transformation of the South African health care system to achieve universal coverage for health services, which includes the creation of a National Health Insurance Fund as a strategy for moving towards Universal Health Coverage (UHC).			
1.2 The aim of universal health coverage is to provide South Africans with—			
(a) access to needed health care that is of sufficient quality to be effective; and			
(b) financial protection from the costs of health care.			
1.3 The National Health Insurance Bill, 2019 (''Bill''), seeks to provide for the universal access to health care services in the Republic in accordance with the National Health Insurance White Paper and the Constitution of South Africa, 1996 (''Constitution''). The Bill envisages the establishment of a National Health Insurance Fund and sets out its powers, functions and governance structures.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
The Fund will purchase health care services for all users who are registered with the Fund. The Bill will also create mechanisms for the equitable, effective and efficient utilisation of the resources of the Fund to meet the health needs of users and preclude or limit undesirable, unethical and unlawful practices in relation to the Fund and its users.			
1.4 The Preamble recognises the socio-economic imbalances and inequities of the past, the need to heal the divisions of the past, the need 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. The Preamble also takes cognisance of Article 12 of the United Nations Covenant on Economic, Social and Cultural Rights, 1966, which provides for the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, and of Article 16 of the African Charter on Human and People's Rights, 1981, which provides for the right to enjoy the best attainable state of physical and mental health. The Preamble also recognises the right to have access to health care services, including reproductive health care as provided in section 27(1)(a) of the Constitution as well as the obligation on the State to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of the right of access to health care services as provided in section 27(2) of the Constitution.			
2. **ADDRESSING BARRIERS TO ACCESS**			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
2.1 Structural challenges in the health system			
2.1.1 There is a need for reform of both the health care financing and service delivery systems so that all South Africans have access to affordable, quality personal health care services regardless of their socio-economic status within the context of the burden of disease in South Africa.			
2.1.2 The main problem relates to the fragmentation of health care fund pools in the South African health system and the aim is to create an integrated pool in order to achieve universal health coverage for health care services by establishing a purchaser-provider split with the Fund being the single-payer for comprehensive health care services purchased on behalf of users.			
2.1.3 The barriers to access that need to be addressed are—			
(a) an onerous burden of out-of-pocket payments on some individuals due to the uneven implementation of user fee exemptions at public hospitals and the high cost of care in the private sector;			
(c) distance to health facilities remains a major barrier to access, including in terms of the availability and costs of public and emergency transport;			

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(c) lack of sufficient, qualified staff within the public health sector relative to the size of the population served by this sector;			
(d) misdistribution of health care providers between geographic areas, with a concentration in large urban areas;			
(e) weak purchasing and incentive mechanisms;			
(f) fragmented funding and risk pools, which limit the potential for income and risk cross-subsidies; and			
(g) inefficient provider payment mechanisms in both the public and the private health sectors.			
2.1.4 In order to achieve the objectives listed below, there must be a reconfiguration of the institutions and organisations involved in the funding, pooling, purchasing and provision of health care services in the South African health system.			
2.2. The implementation of reforms in the 2017/18 to 2021/2022 period will take place in six phases:			
2.2.1 The intermediate preparatory phase involve improving the quality of the health system by first certifying the health facilities to ensure they meet the requirements of the Office of Health Standards Compliance.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
2.2.2 Initiate the establishment of the Fund whilst simultaneously introducing a national quality improvement plan that helps facilities to be certified and accredited to provide health care services to be funded under National Health Insurance (‘‘NHI’’). During this phase health facilities that are certified and accredited will start to provide health care services for users of the Fund (September 2019—March 2021)			
2.2.3 Fund and its Executive Authority will bid for funds through the main budget as part of the budget process to expand coverage using certified and accredited public and private sector health facilities. This phase will focus on fully establishing the purchaser-provider split and associated reforms, such as changing provider payment mechanisms and the implementation of the Fund’s institutional arrangements (May 2020-March 2021).			
2.2.4 Shift some of the conditional grants such as the National Tertiary Services grant and the HIV/AIDS and TB grant from the Department of Health into the Fund and continue with step 2.5.3. (April 2021-March 2022).			
2.2.5 Shifting some or all of the funds currently in the provincial equitable share formula for personal health care services (currently the main public health funding stream to the Fund to gradually extend these delivery and management reforms to all districts and public hospitals (April 2022).			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
2.2.6 The final phase will largely relate to expanding coverage in terms of being able to accommodate the maximum projected utilisation rates and gradually increasing the range of services to which there is a benefit entitlement. In a favourable economic environment there will be an initiation of the evaluation of new taxation options for the Fund including evaluating a surcharge on income tax, a small payroll tax or as financing sources for NHI.			
2.3 This phased approach will be described in more detail in a series of implementation plans by the Department of Health, and will be updated regularly on the basis of insights gained from piloting some of the activities and careful monitoring of each phase.			
2.4 The purpose of the introduction of the reforms mentioned in paragraph 2.2 above is to ensure consistency with the global vision that health care should be seen as a social investment and not be subject to trading as a commodity. The universal health coverage system is a reflection of the kind of society we wish to live in: one based on the values of social solidarity, equity, justice and fairness.			
3. **AFFORDABILITY AND SUSTAINABILITY**			
3.1 A legitimate concern is the affordability and sustainability of National Health Insurance in South Africa. This can best be considered with reference to the nature of the proposed system and the checks and balances that will be put in place to limit unnecessary expenditure increases for supply-side as well as demand-side management.			

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3.2 Affordability and sustainability can be addressed as follows:			
3.2.1 Placing increased emphasis on health promotion and preventive services and outlining how this will be achieved (e.g. through the activities of ward health agents);			
3.2.2 establishing high quality primary health care services as the founda- tion of the health system, to ensure that the majority of health problems can be diagnosed and treated at this level;			
3.2.3 introducing a mechanism for 'gatekeeping' through a primary health care approach and referral system, where patients access higher level services on the basis of referral networks;			
3.2.4 a system of priority setting that emphasises health promotion and disease prevention and in which medically necessary interventions are used; and			
3.2.5 improving public health facility infrastructure and to strengthen district health management.			
3. STRENGTHENING PRIMARY HEALTH CARE ("PHC") SERVICES			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
4.1 Building a high quality and effective PHC service delivery platform is the foundation upon which the health system will be based.			
4.2 The PHC service delivery platform will be located within the District Health Management Offices and services will be delivered in a comprehensive and integrated way.			
4.3 There will be an increased emphasis on health promotion and preventive services, in addition to improving curative and rehabilitative services.			
4.4 The delivery of primary health care services will be population-orientated with extensive use of community and home-based services in addition to PHC facilities, follows:			
4.4.1 PHC outreach teams will be deployed in each municipal ward, supported by a nurse and linked to a PHC facility such as a clinic;			
4.4.2 PHC outreach teams will be allocated households that they will visit on a regular basis. They will provide health promotion education, identify those in need of preventive (e.g. immunisations), or rehabilitative services and refer them to the relevant PHC facility;			

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4.4.3 outreach teams will also facilitate community involvement and participation in identifying health problems and behaviours that place individuals at risk of disease or injury and implement appropriate interventions to address these problems at a community level; and			
4.4.4 school health services will be provided to improve the physical and mental health and general well-being of school going children, including pre-Grade R, and Grade R up to Grade 12.			
4.5 Private primary health care providers will be drawn on to increase service delivery capacity and to improve access to needed health services, especially in under-served rural and informal urban areas.			
4.6 Contracting arrangements will be explored, including improved sessional appointments; contracts to deliver comprehensive PHC services from government health facilities or mobile health posts; and contracts with multi-disciplinary group or network practices operating from private pre- mises.			

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4.7 Contracted private providers will be integrated into the PHC service delivery platform in line with the vision of making comprehensive promotive, preventive, curative and rehabilitative services accessible to all and will be coordinated through the Contracting Units for Primary Health Care (CUPs). They will be an integral part of district health services, contribute not only to clinical service delivery but, where appropriate, also clinical governance activities, and have strong working relationships with other elements of the district health care delivery platform.			
4.8 District Health Management Offices (DHMOs) will be established as government-components reporting to the national sphere to which responsibilities are delegated. Appropriate governance structures will be established at district level to ensure that these institutions serve the public interest.			
4.9 To ensure that the Fund purchases quality health services, the management of hospitals will be decentralised to ensure their effective functioning and sustainability. The delegation of management authority to public hospital facilities will be piloted.			
4.10 Central hospitals will have semi-autonomous boards and administration, management, budgeting and governance functions. The central hospitals will become government components and the competence of the national sphere of government. They will contract directly with the Fund.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
4.11 Provincial tertiary and regional hospitals or groups of hospitals and specialised hospitals will become semi-autonomous entities accountable to the Minister through regulation and whose functions can be delegated to different sphere of government.			
5. OBJECTIVES OF THE BILL			
5.1 Principles			
National Health Insurance will be based on the following overarching principles:			
(a) **Universality** — all will be able to access the same essential health care benefits regardless of their financial means; and			
(b) **Social solidarity** — all regardless of their socio-economic status will benefit from a national system of health care, which is based on income cross-subsidies between the affluent and the impoverished and risk cross-subsidies between the healthy and the sick.			
5.2 **Goal**			
The goal of the National Health Insurance is to move towards universal coverage by serving as a strategic and active purchaser of personal health care services and by—			

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(a) ensuring that the entire population, and not just particular groups, are entitled to benefit from needed, high quality health care;			
(b) extending over time the range of services to which the population is entitled; and			
(c) reducing the extent to which the population has to make direct, out-of-pocket payments for health services.			
5.3 **Objectives**			
The Fund will strive to achieve the following specific objectives:			
(a) universal protection against financial risk;			
(b) equitable distribution of the burden of funding the universal health system:			
(c) equitable and fair provision and use of health services;			
(d) efficiency in service provision and administration;			
(e) quality in service delivery; and			
(f) good governance and stewardship.			
5.4 Applicable Legislation			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
National legislation (as amended) and applicable or related to the contents and mandate of the Bill, and any other legislation that may or may not require amendment at a later stage, include:			

Act No. 63 of 1982	Allied Health Professions Act, 1982	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 130 of 1993	Compensation for Occupational Injuries and Diseases Act, 1993			
Act No. 89 of 1998	Competition Act, 1998			
Act No. 111 of 1998	Correctional Services Act, 1998			
Act No 19 of 1979	Dental Technicians Act, 1979			
Act No. 56 of 1974	Health Professions Act 56 of 1974 as amended			
Act No. 101 of 1997	Higher Education Act, 1997			
Act No. 58 of 1962	Income Tax, 1962			
Act No. 40 of 2002	Institution of Legal Proceedings Against Certain Organs of State Act, 2002			
Act No. 97 of 1997	Intergovernmental Fiscal Relations Act, 1997			
Act No. 28 of 1974	International Health Regulations Act, 1974			
Act No. 117 of 1998	Local Government Municipal Systems Act, 1998 as amended			
Act No. 131 of 1998	Medical Schemes Act, 1998			
Act No. 101 of 1965	Medicines and Related Substances Act, 1965			
Act No. 17 of 2002	Mental Health Care, 2002			

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Act No. 9 of 2009	Money Bills Amendment Procedure and Related Matters Act, 2009	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Act No. 61 of 2003	National Health Act, 2003			
Act No. 32 of 2000	Municipal Systems Act, 2000			
Act No. 37 of 2000	National Health Laboratory Services Act, 2000			
Act No. 33 of 2005	Nursing Act, 2005			
Act No. 78 of 1973	Occupational Diseases in Mines and Works Act, 1973			
Act No. 85 of 1993	Occupational Health and Safety Act, 1993			
Act No. 63 of 1982	Allied Health Professions Act, 1982			
Act No 13 of 2006	Older Persons Act, 2006			
Act No. 53 of 1974	Pharmacy Act 1974			
Act No 70 of 2008	Prevention of and Treatment for Substance Abuse Act, 2008			
Act No. 56 of 1996	Road Accident Fund Act, 1996			
Act No. 35 of 2007	Traditional Health Practitioners Act, 2007			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
6. **CLAUSE BY CLAUSE ANALYSIS**			
6.1 **Clause 1**			
Clause 1 provides for the definitions of the Bill.			
6.2 **Clause 2**			
Clause 2 provides for purpose of the Bill.			
6.3 **Clause 3**			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Clause 3 provides for the scope and application of the Bill.			
6.4 **Clause 4**			
6.4.1 Clause 4 deals with the eligibility to become a beneficiary of the Fund. Clause 4 provides that the Fund must, in consultation with the Minister, purchase comprehensive health service benefits as deter- mined by the Benefits Advisory Committee of the Fund on behalf of—			
(a) South African citizens;			
(b) persons who are permanently resident in the Republic;			
(c) the dependants of persons referred to in paragraphs (a) and (b);			
(d) all children, including children of asylum seekers or illegal immigrants are entitled as provided for in section 28 of the Constitution; and			
(e) all inmates as provided for in section 12 of the Correctional Services Act.			
6.4.2 This clause also provides that an asylum seeker or illegal foreigner is only entitled to emergency medical services and service for notifiable candidates of public health concern.			
6.5 **Clause 5**			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Clause 5 of the Bill deals with the registration as users with the Fund and for, amongst others, the presentation of an identity document, smart card, valid permit or visa in terms of the provisions of the Refugees Act, 1998 (Act No. 130 of 1998), or the Immigration Act, 2002 (Act No. 13 of 2002), as the case may be, for persons intending to register with the Fund.			
6.6 **Clause 6**			
Clause 6 deals with the rights of the users of the Fund. These include, amongst others, the right to receive quality health care services free of charge from certified and accredited health care service providers and health establishments upon presentation of proof of registration.			
6.7 **Clause 7**			
Clause 7 provides that the Fund will purchase health care service as determined by the Benefits Advisory Committee in consultation with the Minister for the benefit of users who are registered with the Fund			
6.8 **Clause 8**			
Clause 8 deals with the cost coverage in relation to the Fund. This clause provides that a person who is registered as a beneficiary will receive the required services as purchased on his or her behalf by the Fund from certified and accredited health care service providers at no cost.			
6.9 **Clause 9**			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Clause 9 provides for the establishment of the Fund as a national public entity as contemplated in the Public Finance Management Act, 1999 (Act No. 1 of 1999) (‘‘PFMA’’).			
6.10 **Clause 10**			
Clause 10 contains a list of functions of the Fund.			
6.11 **Clause 11**			
Clause 11 contains a list of the powers of the Fund.			
6.12 **Clause 12**			
Clause 12 makes provision for the establishment of an independent Board that is accountable to Parliament in accordance with the provisions of the PFMA.			
6.13 **Clause 13**			
Clause 13 makes provision for the constitution and composition of the Board. It sets out the process for the nomination of candidates to serve on the Board and the role of the ad-hoc panel tasked with interviews of the shortlisted candidates and making recommendations to the Minister of Health (‘‘Minister’’) for his appeal. Clause 13 also outlines the conditions in terms of which the Minister may dissolve the Board after consultation with the Portfolio Committee.			
6.14 **Clause 14**			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Clause 14 deals with the appointment of the Chairperson and Deputy Chairperson of the Board.			
6.15 **Clause 15**			
Clause 15 makes provision for the functions and powers of the Board. In terms of this clause, the Board must fulfil the functions of an accounting authority in terms of the provisions of the PFMA and is accountable to Parliament. The Board shall advise the Minister on any matter concerning—			
(a) the management and administration of the Fund;			
(b) the improvement of efficiency and performance of the Fund in terms of universal purchasing and provision of health care services;			
(c) terms and conditions of employment of Fund employees;			
(d) collective bargaining; and			
(e) the budget of the Fund.			
6.16 **Clause 16**			
Clause 16 deals with the conduct and disclosure of interests by members of the Board.			
6.17 **Clause 17**			
Clause 17 makes provision for the Board to determine its own procedures.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
6.18 **Clause 18**			
This clause deals with the remuneration and reimbursement of members of the Board.			
6.19 **Clause 19**			
Clause 19 makes provision for the appointment of the Chief Executive Officer (‘‘CEO’’) of the Fund. The CEO shall 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.			
6.20 **Clause 20**			
Clause 20 provides that the CEO is directly accountable to the Board and his or her responsibilities include, amongst others—			
(a) the formation and development of an efficient Fund administration;			
(b) the organisation and control of the staff of the Fund;			
(c) the maintenance of discipline within the Fund;			
(d) the effective deployment and utilisation of staff; and			
(e) the establishment of an Investigating Unit within the national office of the Fund.			
6.21 **Clause 21**			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Clause 21 provides for the relationship of CEO with the Minister, Director- General and Office of Health Standards Compliance.			
6.22 **Clause 22**			
Clause 22 deals with the power of the CEO in relation to the appointment and dismissal of the executive management officials of the Fund.			
6.23 **Clause 23**			
Clause 23 empowers the Minister to appoint technical committees.			
6.24 **Clause 24**			
Clause 24 empowers the Board to establish technical committees.			
6.25 **Clause 25**			
Clause 25 makes provision for the appointment of a Benefits Advisory Committee by the Minister, after consultation with the Board.			
6.26 **Clause 26**			
Clause 26 provides that the Minister must, after consultation with the Board, establish a Health Care Benefits Pricing Committee.			
6.27 **Clause 27**			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Clause 27 makes provision for the appointment of a Stakeholder Advisory Committee by the Minister, after consultation with the Board.			
6.28 **Clause 28**			
Clause 28 provides for the disclosure of interests by members of a committee.			
6.29 **Clause 29**			
Clause 29 provides for the remuneration and procedures of a committee that is established by the Minister in terms of clause 23 of the Bill and empowers the Minister to determine the remuneration and procedures in respect of such a committee.			
6.30 **Clause 30**			
Clause 30 provides for vacation of office by members of the committee.			
6.31 **Clause 31**			
Clause 31 provides for the legislative role of the Minister in relation to the governance and stewardship of the national health system and the governance and stewardship of the Fund.			
6.32 **Clause 32**			
Clause 32 provides for the legislative role of the Department as contemplated in the National Health Act, 2003 (Act No. 61 of 2003) (‘‘National Health Act’’).			

6.33 **Clause 33**	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Clause 33 deals with the role of medical schemes. In terms of this clause, medical schemes registered in terms of the Medical Schemes Act, 1998 (Act No 131 of 1998), or any other voluntary private health insurance scheme, shall be restricted to providing complementary cover for health care service benefits that are not purchased by the Fund on behalf of users.			
6.34 **Clause 34**			
Clause 34 provides for the National Health Information System.			
6.35 **Clause 35**			
Clause 35 provides for the purchasing of health services by the Fund. The Fund shall actively and strategically purchase health care services on behalf of users in accordance with need and the provisions of this Act.			
6.36 **Clause 36**			
Clause 36 provides for the role of District Health Management Offices. The District Health Management Office established by section 31A of the National Health Act must facilitate, coordinate and manage the provision of non- personal public health care programmes at district level in compliance with national policy guidelines and applicable law.			
6.37 **Clause 37**			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Clause 37 makes provision for the establishment of the Contracting Unit for Primary Health Care. The Contracting Unit is the organisational unit with which the Fund contracts for the provision of primary health care services within a specified geographical sub-district area.			
6.38 **Clause 38**			
Clause 38 provides for the establishment by the Minister of the Office of Health Products Procurement that is accountable to the Board of the Fund.			
6.39 **Clause 39**			
Clause 39 provides for accreditation of public and private health establishments by the Fund.			
6.40 **Clause 40**			
Clause 40 deals with the payment of service providers of the Fund. In terms of the clause, the Fund, in consultation with the Minister, will determine the nature of service provider payment mechanisms and adopt mechanisms to establish that health care service providers, health establishments and suppliers are properly accredited in terms of clause 39, before they receive payment.			
6.41 **Clause 41**			
Clause 41 provides that an affected natural or juristic person, namely a user, health care service provider, health establishment or supplier, may lodge a complaint with the Fund in consultation with the Minister and the Fund must deal with such complaints in a timeous manner and in terms of applicable law.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
6.42 **Clause 42**			
Clause 42 deals with the lodging of complaints with a Fund.			
6.43 **Clause 43**			
Clause 43 deals with the lodging of appeals to the Appeal Tribunal against a decision as contemplated in clause 42.			
6.44 **Clause 44**			
Clause 44 deals with the establishment of the Appeal Tribunal, its composition and the term of office of its members.			
6.45 **Clause 45**			
Clause 45 makes provision for the powers of the Appeal Tribunal.			
6.46 **Clause 46**			
Clause 46 provides for the designation of the secretariat of the Appeal Tribunal.			
6.47 **Clause 47**			
Clause 47 provides for the remuneration and procedures of the Appeal Tribunal.			
6.48 **Clause 48**			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Clause 48 makes provision for the sources of income of the Fund. In terms of clause 48, the South African Revenue Service will undertake all revenue collection related to the Fund, including the collection of any supplementary health tax levies if applicable. The Treasury will, in consultation with the Minister of Finance, the Minister and the Fund, determine the budget and allocation of revenue to the Fund on an annual basis.			
6.49 **Clause 49**			
Clause 49 provides for the chief source of income of the Fund.			
6.50 **Clause 50**			
Clause 50 deals with the auditing of the books of the Fund.			
6.51 **Clause 51**			
Clause 51 provides that the Board, as the accounting authority of the Fund, must submit to the Minister an annual report on the activities of the Fund during each financial year. Furthermore, the clause makes provision for the requirements of the annual report in terms of its content and the obligation on the Minister to table the annual report in the National Assembly and the National Council of Provinces without delay.			
6.52 **Clause 52**			
Clause 52 deals with the assignment of duties and delegation of powers of the Fund.			

6.53 **Clause 53**	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
Clause 53 makes provision for the protection of confidential information.			
6.54 **Clause 54**			
Clause 54 creates a list of offences in instances where a natural or juristic person contravenes specific provisions in the Bill.			
6.55 **Clause 55**			
Clause 55 makes provision for the powers of the Minister to make regulations.			
6.56 **Clause 56**			
Clause 56 makes provision for the powers of the Fund to issue directives.			
6.57 **Clause 57**			
Clause 57 deals with transitional arrangements in respect of the Bill.			
6.58 **Clause 58**			
Clause 58 deals with the repeal and amendment of laws as provided in the Schedule to the Bill.			
6.59 **Clause 59**			
Clause 59 provides for the short title and commencement.			
7. **DEPARTMENTS/BODIES CONSULTED**			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
National Health Council			
National Treasury			
Forum of South African Directors General			
Public Consultations through 197 received and evaluated written comments			
Civil Society			
Traditional Leaders			
Health Professional Groups			
Finding intermediaries			
8. **FINANCIAL IMPLICATIONS FOR THE STATE**			
The Fund will be financed in various interrelated phases as determined in consultation with the National Treasury:			
8.1 The costing/budgeting focuses on practical issues, rather than general models (three of which were previously contracted). The latest focuses on three issues:			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
(a) Quality of care improvement programme: The War-room is of the view that a new funding component is required to accelerate quality initiatives, to support a stronger response post OHSC audit and also to support progressive accreditation of facilities for Fund. Amounts of R75 million, R125 million and R175 million will be considered for potential reprioritisation as part of the budget process.			
(b) Establishment of Fund: The preliminary costing is R57 million, R145 million and R287 million. These should be seen as ideal and will probably be less given practical delays e.g. in passing Bill. Again in the short term these funds can largely be found through reprioritisation within the grant.			
(c) Actuarial costing model: Treasury commissioned a simplified interven-tion-based costing tool for 2019/20 which provides simple estimates of costs of a set of 15 or so interventions. These include for example removing user fees, extending chronic medicine distribution programme (CCMDD), extending ARV rollout, increasing antenatal visits, rolling out capitation model for General Practitioners (GPs), cataract surgery programme, establishing Fund. The full set of interventions costs in the longer term around R30 billion per annum. The Department will adapt the tool to find a set of priority interventions. Most of these interventions can be scaled up progressively as funding becomes available and does not need significant new funds in Budget 2020.			
8.2 The Human Resources Capacitation Grant will be used to appoint staff to ensure implementation of the Fund already increases from R330 million spending in 2018/19 to R600 million in 2019/20 to R1 billion in 2020/21 and R1.1 billion in outer years. This should be focussed in the first instance on statutory posts such as interns and community service, given problems in provinces funding these key posts and national interest in making sure these are fully funded.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
8.3 The above is preliminary work and to be taken forward will need to be further developed around Budget 2020.			
8.4 The rising Fund budget baseline (R4.2 billion was reprioritised from tax subsidy; NHI grant rises from R2.5 billion in 2019/20 to R3.1 billion in 2020/21) and under-spending in 2018/19 (around R600 million), requires that most of the short term funding for the above is derived from reprioritisation and rising baseline. The 2020/21 budget of R3.1 billion is already substantially above 2018/19 spending of R 1.7 billion.			
8.5 In the next phase the Fund and its Executive Authority will be able to bid for funds through the main budget as part of the budget process.			
8.6 Thereafter consideration will be given to shifting some of the conditional grants such as the National Tertiary Services grant and the HIV/AIDS and TB grant from the Department to the Fund. Preliminary analysis suggests this will require legal amendments.			
8.7 The table below outlines the 2019 MTEF Fund Conditional Grant allocations:			

Non-Personal Services Component	**758,000**	**832,000**	**858,860**
CCMDD	420,000	476,000	483,280
Ideal Clinic Component	23,000	26,000	27,430
Information Systems	315,000	330,000	348,150
Medicine Stock Surveillance System	143,000	150,000	158,250

Health Patient Registration System	172,000	180,000	189,900
Personal Services Component	**639,288**	**783,000**	**915,068**
HP Contracting Current Model (contr - In)	289,288	305,198	321,053
GP Contracting - Capitation	150,000	200,000	211,000
Mental Health Services	100,000	125,000	150,000
Other priority services (Oncology)	100,000	152,802	233,015
Total NHI Indirect Grant	**2,533,699**	**3,210,816**	**3,336,016**
Total Conditional Grants Allocation (Direct & Indirect)	47,522,518	52,435,758	57,424,345

	2019 MTEF Allocations		
	2019/20	**2020/21**	**2020/21**
Direct Grants	**R'000**	**R'000**	**R'000**
Health Prof Training and Dev Grant	2,940,428	3,102,152	3,272,770
National Tertiary Services Grant	13,185,528	14,068,863	14,842,650
Comprehensive HIV and AIDS, TB & COS	**22,038,994**	**24,408,471**	**27,752,587**
HIV/AIDS Component	19,963,269	22,195,284	24,518,748
TB Component	485,300	511,989	540,151
Community Outreached Services Component	1,500,000	1,584,000	2,582,500
Malaria Component	90,425	117,198	111,188
Health Facility Revitalisation Grant	6,006,973	6,359,557	6,858,024
Human Papillomavirus (HPV)	211,200	222,816	235,071
Human Resources Capacitation Grant	605,696	1,063,083	1,127,227

TOTAL	**44,988,819**	**49,224,942**	**54,088,329**

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
8.8 In a later phase consideration will be given to shifting of funds currently in the provincial equitable share formula for personal health care services (currently the main public health funding stream consisting of around R150 billion per annum) to the Fund. This will require amendments to the National Health Act, 2003. This will also depend on how functions are shifted, for example if central hospitals are brought to the national level.			
8.9 Chapter 7 of the Fund White Paper details several new taxation options for the Fund, including evaluating a surcharge on income tax, a small payroll-based taxes as financing sources for the Fund. Due to the current fiscal condition, tax increases may come at a later stage of NHI implementation			
9. **PARLIAMENTARY PROCEDURE**			

Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
9.1 The Constitution regulates the manner in which legislation may be enacted by Parliament and prescribes the different procedures to be followed for such enactment. Section 76 of the Constitution provides for the parliamentary procedure for ordinary Bills affecting the provinces. In terms of section 76(3) a Bill must be dealt with in accordance with the procedure established by either section 76(1) or section 76(2) if that Bill provides for legislation envisaged in section 76(3)(a) to (f) or if it falls within a functional area listed in Schedule 4.			
9.2 **In Tongoane and Others v National Minister for Agriculture and Land Affairs and Others** i **(''Tongoane** judgment''), the CC confirmed and upheld the test for tagging that was formulated in **Ex Parte President of the Republic of South Africa: In re Constitutionality of the Liquor Bill** ii, where the CC held that— ''the heading of section 76, namely, 'Ordinary Bills affecting provinces' provides a strong textual indication that section 76(3) must be understood as requiring that any Bill whose provisions in substantial measure fall within a functional area listed in Schedule 4, be dealt with under section 76.''.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
9.3 At paragraph 50 of the Tongoane judgment the CC held that the tagging test focuses on all the provisions of the Bill in order to determine the extent to which they substantially affect the functional areas listed in Schedule 4 and not on whether any of its provisions are incidental to its substance.			
9.4 The CC stated the following at paragraph 58 of the Tongoane judgment: ''What matters for the purposes of tagging is not the substance or the true purpose and effect of the Bill, rather, what matters is whether the provisions of the Bill 'in substantial measure fall within a functional area listed in Schedule 4'.''.			
9.5 The CC further held that the test for tagging must be informed by its purpose. Tagging is not concerned with determining the sphere of government that has the competence to legislate on a matter. Nor is the purpose concerned with preventing interference in the legislative competence of another sphere of government.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
The process is concerned with the question of how the Bill should be considered by the provinces and in the National Council of Provinces, and how a Bill must be considered by the provincial legislatures depends on whether it affects the provinces. The more it affects the interest, concerns and capacities of the provinces, the more say the provinces should have on its content.iii			
9.6 To determine whether the provisions of the Bill in substantial measure fall within a functional area listed in Schedule 4, the Bill ought to be considered against the provisions of the Constitution relating to the tagging of Bills as well as against the functional areas listed in Schedule 4 and Schedule 5 to the Constitution.			
9.7 The test compels the consideration of the substance, purpose and effect of the subject matter of the Bill. In view of the discussion above and after careful scrutiny of all the provisions in the Bill, we are of the opinion that the Bill in substantial measure falls within the ambit of ‘‘health services’’ which is an area listed in Part A of Schedule 4, which makes provision for functional areas of concurrent national and provincial legislative competence. As such, the State Law Advisers and the Department of Health are of the opinion that the Bill must be tagged as a section 76 Bill.			

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Clause/Section	Comment/Amendment	Rationale/Substantiation	Proposed Correction if required
9.8 The State Law Advisers are of the opinion that there is no need for a referral of the Bill to the National House of Traditional Leaders as it contains no provisions pertaining to customary law or the customs of traditional communities as envisaged in section 18(1)(a) of the Traditional Leadership and Governance Framework Act, 2003 (Act No. 41 of 2003.)			

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Addendum 2: International models

	Procurement	Pricing / Reimbursement Models	Funding Models / Mechanisms	Regulatory Aspects	Other / Success / Failures
Thailand (2002)	UCS purchases comprehensive services including medicines on National List of Essential Medicines for US beneficiaries as well as for health promotion and disease prevention for all Thais. CMBS does like UCS but also non-essential medicines if physician recommended.	UCS has a mixed provider payment-based age adjusted capitation paid to district health system, based on number of registered users in the catchment populations. Cost of outpatient referral to higher responsibility networks. Hospitals are paid by DRG with national global budget. Single base rate per relative weight is applied to all levels of the hospital (private and public). High cost interventions such as dialysis, chemotherapy, antiretroviral treatment paid on a dee schedule. Health promotion and prevention mostly paid on a capitation bases with some combination of fee schedules.	Three public health insurance schemes: The Social Health Insurance (SHI), The Civil Servants Medical Benefit Scheme (CSMBS) and the Universal Coverage Scheme (UCS). SHI: is a contributory scheme for private workers managed by the Social Security Office of the Labour Ministry.	Regulator: Thailand Food and Drug Administration. Medical devices are classified as follows: Class I (high risk), Class II (moderate risk) e Class III (low risk). Quality System requirement is ISO 13485:2016 and a Thailand Authorized Representative is required. Class I devices must be registered with the Regulatory Authority, therefore it is necessary to submit the required documentation in the Common Submission Dossier Template (CSDT) format which will be subject to an in-depth revision. If successful, the Regulatory Authority will issue the Licence for Sale	

	Procurement	Pricing / Reimbursement Models	Funding Models / Mechanisms	Regulatory Aspects	Other / Success / Failures
		CSMBS fee for service taken away in favour of mixed provider payment. All outpatient services are a fee-for service directly disburse from CGD to healthcare providers on monthly basis. Inpatient services are paid by DRG without a global budget, varying DRG rates are applied, with higher rate for teaching hospitals than district hospitals. High cost interventions are paid by fee schedule, but higher rates than UCS.	CSMBS is tax financed non-**contributory covering government employees and their dependents and is managed by Comptroller General Department of the Ministry of Finance. UCS is tax financed non-contributory covering the remaining 75% of the population and is managed by the National** Health Security Office.	Class II devices must be notified to the Regulatory Authority; therefore it is necessary to submit the required documentation in the Common Submission Dossier Template (CSDT) format for the revision that will be less detailed compared to Class I devices one. If successful, the Regulatory Authority will issue the Notification. Class III devices, on the other hand, must be validated by the Regulatory Authority which will issue the Certificate for Custom Process after the revision. As regards sterile medical devices it is necessary to submit the ISO 13485:2016 certification	
Singapore (2001)	Purchase of goods through centralised Group Procurement Offices (GPOs) by way of tender contracts, this operates in some way to regulate prices of therapeutic products and medical devices. Medical Assistance Fund and Standard Drug List ensure patients have access to effective medications for common conditions.	The prices of therapeutic products (including biological therapeutic products) and medical devices are generally not regulated by the Singapore government	Mix financing system providing multiple tiers of financing for citizens and residents. Singapore's national healthcare system is funded by a mixed financing system, comprising multiple tiers of financing for Singaporeans' healthcare expenditure. There are broadly four tiers of healthcare funding, namely:	Medical Technology needs to be registered with the HAS with a local company, subject to exceptions: custom made medical devices, medical devices which have undergone maintenance or repair, medical devices for patient use, Class A devices and medical devices for clinical research.	Singapore adopts a mixed delivery healthcare model, with primary healthcare services, acute hospital services and step-down care services being offered by healthcare providers in both the public and private sectors. Briefly, the distribution of services provided by the public and private sectors is as follows:

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	Procurement	Pricing / Reimbursement Models	Funding Models / Mechanisms	Regulatory Aspects	Other / Success / Failures
		However, public sector hospitals in Singapore generally purchase medicinal products through centralised Group Procurement Offices (GPOs) by way of tender contracts, and this operates in some way to regulate the prices of therapeutic products and medical devices. The national healthcare system in Singapore operates on mixed financing system that provides multiple tiers of financing for its citizens and residents. Apart from direct subsidies for services and drugs at public healthcare institutions, the Singapore government also administers a number of drug subsidy schemes.	Direct subsidies from the Singapore government for all Singaporeans, of up to eighty per cent (80%) of the total bill in acute public hospital wards; Medisave, which is a compulsory individual medical savings account scheme under which every working Singaporean as well as his employer must contribute a portion of his monthly wages into the account to save for his future medical needs;	Also Class A, B, C & D based on risk classification of medical device. A, B & C Class on IVDs based on a separate risk model. The risk classification will affect the registration requirements and the evaluation route that applies to that registration. The relevant product evaluation route will also dependent on whether device has received reference agency approvals and the prior safe marketing history of the device.	Primary care sector: Private sector providers account for around 80% of the market. Acute care sector: Public sector providers account for around 80% of the market. Step-down care sector: Voluntary welfare organisations, most of which are funded by the government for services provided, account for a majority of the market

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	Procurement	Pricing / Reimbursement Models	Funding Models / Mechanisms	Regulatory Aspects	Other / Success / Failures
		These include the Medication Assistance Fund (see Chapter 1, Question 10) and the Standard Drug List, to ensure that eligible patients have access to effective medications for medical conditions that are common in Singapore.	Insurance plans such as MediShield Life, which is a basic, low-cost medical insurance scheme for all Singaporeans and permanent residents, which helps to pay for large hospital bills and specified costly outpatient treatments, including dialysis and chemotherapy; and MediFund, which is a medical endowment fund established by the Singapore government to further aid needy Singaporean patients who are unable to pay for their remaining medical bills even after using other means of payment (including the abovementioned tiers of financing).	Registration applications are handled online through HAS's MEDICS web portal. Non-sterile Class A medical devices are exempt from registration, but an application is required as established by ASEAN. Devices already registered in other countries (European Union, Japan, USA, Canada, Australia) may be eligible for an immediate registration procedure.	

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	Procurement	Pricing / Reimbursement Models	Funding Models / Mechanisms	Regulatory Aspects	Other / Success / Failures
Australia	The Medical Services Advisory Committee (MSAC) provides advice to the Minister of Health on medical procedures for listing on the Medicare Benefits Schedule, including services and procedures related to diagnostic tests and medical devices. The principal role of MSAC is to evaluate new medical technologies and procedures, based on evidence of their comparative safety, clinical effectiveness, and cost-effectiveness.	The DoH considers eligibility to ensure the proposed service constitutes a clinically relevant service under the criteria of the Health Insurance Act 1973, the need for Therapeutic Goods Administration (TGA) approval of products, and the confirmation from the MSAC Executive of the assessment pathway	Financing for health care is provided by the Australian Government, or State, Territory, and Local governments, as well as private health insurance and out-of-pocket payments by individuals.	Therapeutic Good Administration (TGA) is regulatory authority. Classification is I, IIa, IIb, III. ISO 13485:2016. Medical devices and IVDs are subject to registration, which means including them on the Australian Register of Therapeutic Goods (ARTG).	

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	Procurement	Pricing / Reimbursement Models	Funding Models / Mechanisms	Regulatory Aspects	Other / Success / Failures
				Foreign manufacturers who intend to market their medical devices in Australia must appoint a Sponsor, a Local Authorized Representative responsible for submitting the documents required for the registration process to the TGA The Therapeutic Goods Administration (TGA) is the regulatory body for therapeutic goods in Australia. The TGA's regulatory requirements vary, depending on what the device is and how it is to be used. The risks associated with using medical devices to patients and users can range from little or low potential risk to significant potential risks. The level of assessment performed by the TGA before the device is approved for use in Australia directly relates to the level of potential risk. The key elements of the medical device regulatory scheme include:	

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	Procurement	Pricing / Reimbursement Models	Funding Models / Mechanisms	Regulatory Aspects	Other / Success / Failures
				• Product requirements (the Essential Principles) for the quality, safety, and performance of the medical device that must be complied with before and after the device is supplied to the market in Australia • A device classification scheme based on different levels of risk.	
		They can prepare and submit a Submission-Based Assessment (SBA) that collates the evidence on efficacy, safety and cost-effectiveness of the proposed technology.	In the overall funding arrangements, the Australian Government provides funding for most out of hospital medical services and for health research.	• Options as to how compliance with the Essential Principles can be demonstrated	

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	Procurement	Pricing / Reimbursement Models	Funding Models / Mechanisms	Regulatory Aspects	Other / Success / Failures
		The SBA is then critiqued by a contracted HTA Group. Assessment reports are published on DoH website and are publicly available. Before submitting evidence for MSAC approval, all therapeutic goods used in the relevant medical service should have been either listed on the Australian Register of Therapeutic Goods, or, an application for listing lodged with the TGA. If a decision is made to publicly approve the proposed service/device, DoH is instructed to implement the changes.	The Australian, State, and Territory governments jointly fund public hospitals and community care for aged and disabled persons. Australian funding for health care is raised principally through general taxation (such as income tax, and taxes on sales of goods and services) and is supplemented by the 2.0% Medicare levy on taxable income above certain income thresholds. The Medicare levy was 1.5% prior to July 2014, with the extra 0.5% dedicated exclusively to fund the NDIS.	• The optional use of recognized standards • Ongoing monitoring of medical devices that are available on the market • Regulatory controls for the manufacturing processes of medical devices • The Australian Register of Therapeutic Goods (ARTG) as the central point of control for the legal supply of medical devices in Australia • The provision for imposing penalties where regulatory requirements are breached • A range of corrective actions that may be taken if there is a problem with a device	

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	Procurement	Pricing / Reimbursement Models	Funding Models / Mechanisms	Regulatory Aspects	Other / Success / Failures
		For example, if a new MBS item has been approved, the item is added to the Medicare Benefits Schedule that describes the service and the fee on which the Medicare benefit is based. Of note is that the MBS item is generic; that is, it is not linked to a specific product. There are two main categories of implantable medical devices. No-gap devices are listed with a single benefit and health insurers are required to pay if the patient has appropriate insurance coverage. Gap-permitted devices have minimum and maximum benefits listed. For gap-permitted implantable devices, private health insurers are required to pay at least the minimum benefit, and a co-payment is charged to the patient.	There are also significant co-payments on many services (relative to many developed countries), especially for specialists and drugs. Taxpayers with high incomes who do not have private health insurance pay an additional 1% to 1.5% of taxable income as part of the levy. Medicare levy revenue raised AUD$9 billion or around 50% of the cost of Medicare services in 2011-12 [1]. Private Health Insurance Rebate is an Australian Government tax rebate scheme to encourage participation in private health insurance membership. Currently, the Australian Government provides up to 38.7% subsidy to individuals who acquire private health insurance, depending on age and income. As of December 2013, 47% of the population was covered by basic private health insurance [2]		

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	Procurement	Pricing / Reimbursement Models	Funding Models / Mechanisms	Regulatory Aspects	Other / Success / Failures
United Kingdom	Consideration is given to: Compatibility with existing medical devices, Maintenance, Training, Routine cleaning/disinfection/sterilisation, device education and training materials, support from manufacturer, cost of consumables and lifetime cost, disposal of, availability of quotations, service models, acceptance of user testing, trust/trial period before signing off. Procurement similar to SA private sector, however, on capital equipment servicing and maintenance is handled by hospital and not manufacturer. Clinical partners, financial partners, suppliers area all part of selection of device and treatment – not only the funders. NICE is the most important organisation to introduce new technologies in the UK health system. NICE conducts appraisals and develops guidelines whereas the NCCHTA manages and develops the NHS HTA programme.	Financial implications are considered with potential future costs associated downstream. Suppliers and their input form part of the reimbursement model. CE marked medical device is reviewed by NICE. This organization appraises the interventions that impact health benefits, government policies and NHS resources to then issue national guidance for care. New technologies are appraised by NICE through one of three routes:	The UK's healthcare system is single payer and is primarily public, with 80% of the funding coming from taxation. As a public health system, the NHS provides public healthcare to all of its permanent residents which is free at the point of need. Clinical Commissioning Groups (CCGs) are responsible for providing NHS healthcare services to local populations, having taken over from Primary Care Trusts in 2013. There are currently 207 CCGs in England supported by Clinical Commissioning Units, and CCGs are responsible for approximately ⅔ of the total NHS England budget - or £73.6 billion in 2017/18.	Medical device manufacturers will have to follow separate device approval processes for EU and UK and appoint a UK Responsible Person	The NHS was rated as the world's best healthcare system in 2017 and stands out as a top performer in most categories. However, as the UK population continues to increase to a projected 71.04 million by 2030 and as the average age is expected to rise to 42.8 by 2037, the NHS is being put under serious strain and faces severe funding challenges - which will of course have a direct impact on medical device pricing and reimbursement.

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	NICE is an independent organisation established to produce national guidance on specific health technology including both medicines and medical devices as well as clinical practice. It runs many different programmes and looks at medical devices in many ways, from safety to efficacy through to patient, system and economic benefit. NICE guidance helps the NHS to adopt effective and cost-efficient technologies and procedures and is highly influential across the world	• Multiple Technology Appraisals (MTAs) usually covers more than one technology, or a single technology to be used in more than one indication • Single Technology Appraisal (STAs) forms cover a single technology to be used in a single indication • Fast Track Approval (FTA) this form covers a single technology used in a single indication, however it is typically for shorter process time so that it can speed access to novel cost-effective treatments Each process consider evidence on the health effects, costs and cost-effectiveness of a health technology. Having received approval by NICE the product can be listed in the BNF (British National Formulary), however it is not until individual CCGs grant access to.			

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		Typically, CCGs the product in their region that it can be reimbursed will go to tender to select formulary devices. Progressively CCGs are forming larger regional groups for evaluating devices for inclusion on formulary and for devices which are used in both hospital and out of hospital, making joint decisions. The publicly funded NHS reimbursement system doesn't reward clinicians financially for performing a procedure and there are no specific product related codes either. Instead, clinicians are simply paid an annual salary. This means that unlike other markets and different countries, you don't need to negotiate with hundreds of insurance companies; it is the CCGs' responsibility to pay hospitals for performing procedures, which is why they are now often			

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		referred to as payers.			
		The NHS reimbursement system works according to the following: • The diagnosis of the patient by ICD code • The procedure/procedures performed by OPCS code • Length of stay and type of admission • The location of the hospital All of the information is input into a computer system called a grouper, resulting in a HRG or DRG code which has a financial value or tariff. The hospital then claims the amount for the procedure from the CCG every month by a payment system called SUS.			

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