Unit 16, Northcliff Office Park, 203 Beyers Naude Drive
Northcliff, Johannesburg, 2115, South Africa
Tel: (+27)(11) 340 9000, Fax: (+27)(11) 782 0270
Email: info@healthman.co.za
PO Box 2127, Cresta, Johannesburg, 2118, South Africa
Registration No.: 1996/14778/07
VAT Reg.# 4190163982

Commentary by HealthMan

to the Portfolio Committee on Health
National Parliament of the RSA

on Bill 11 of 2019
Proposed National Health Insurance Act

29 November 2019

Note: in this submission, for ease of reference, clauses in the Bill is referred to as "sections", and the Bill will be referred to as the "PNHIA" for the proposed NHI Act" or "the Bill".

Abbreviations:

ARM: Alternative Reimbursement Model
BAC: Benefits Advisory Committee
BPC: Benefits Pricing Committee
CMS: Council for Medical Schemes
CON: Certificate of Need
CPA: Consumer Protection Act
CSIR: Council for Scientific and Industrial Research
CUP(s): Contracting Unit(s) for Primary Health Care
DG: Director-General of Health
DHMO: District Health Management Office
DRG: Diagnosis-related group
DTC: Davis Tax Committee
EEL: Essential Equipment List
EML: Essential Medicines List
FDCA: Foodstuffs, Cosmetics and Disinfectants Act, 1972
HPA: Health Professions Act, 1974
HPCSA: Health Professions Council of SA
HPRS: Health Patient Register System
HMI: Health Market Inquiry
HTA: health technology assessment
IVD: in vitro diagnostic device
MOH: Minister of Health
MTBPS: Medium Term Budget Policy Statement
MPs: Members of Parliament
NRCS: National Regulator for Compulsory Specifications
NDOH: National Department of Health
NHA: National Health Act, 2003
NHC: National Health Council
NHIF: National Health Insurance Fund
NHIS: National Health Information System
OHPP: The Office of Health Products Procurement
OHSC: Office of Health Standards Compliance
OSLA: Office of the State Law Advisor
PEPUDA: Promotion of Equality and Prevention of Unfair Discrimination Act
PES: Provincial Equitable Share
PFMA: Public Finance Management Act, 1999
PAIA: Protection of Personal Information Act, 2000
PDOH(s): Provincial Department(s) of Health
PHC: Primary Health Care
PNHIA: Proposed NHI Act, in form of Bill 11 of 2019
PMBs: Prescribed Minimum Benefits, as set under the Medical Schemes Act, 1998
POPIA: Protection of Personal Information Act, 2013
PSA: Public Service Act, 1994
PSCBC: Public Service Co-ordinating Bargaining Council
SAHPRA: South African Health Products Regulatory Authority
SALRC: South African Law Reform Commission
SANAS: South African National Accreditation System
SANC: SA Nursing Council
SAPC: SA Pharmacy Council
SAPPF: South African Private Practitioners Forum
SSRH: Supply Side Regulator for Health

1. Who we are

HealthMan is a privately owned healthcare consultancy specialising in the management and administration of specialists' societies and other provider healthcare networks.

Our concentrated focus on promoting the professional and commercial interests of both specialist networks and other healthcare practitioner groupings, coupled with our extensive industry contracts, make us the preferred choice for healthcare professional group administration in South Africa. HealthMan consults to over 5 000 practitioners in South Africa and Namibia.

HealthMan was founded in 1996 and since inception has focused mainly on consulting to private practice. Our areas of expertise include network administration, legal support, healthcare research, financial modelling, assisting societies with financial and governance matters as well as the publication of various medical scheme rates of reimbursement and our own wholly independently determined and funded costing assessment.

HealthMan consultants play pivotal communication, representation and negotiation roles in our relations with key healthcare industry stakeholders: Healthcare Practitioner Networks, Funders (i.e. Medical Schemes, Administrators and Managed Healthcare Organisations), Professional Associations, Hospitals, Pharmaceutical Companies, Regulatory Authorities and Suppliers of Consumables and Equipment.

In addition to consulting in the Healthcare industry, HealthMan performs outsourced administration services to a variety of clients. The company has also been involved in management and initiations on Alternative Reimbursement Models (ARMs), both Global- and Capitation Fee contracts.

2. Overarching comments on matters of principle

2.1. Constitutionality of the PNHIA

During discussions at the Health Portfolio Committee in Parliament on 29 August 2019, MPs were assured of the constitutionality of the PNHIA by the Office of the State Law Advisor (OSLA).

HealthMan submits that this is not the case in four respects:

(a) Compliance with the Bill of rights, notably sections 27 (access to healthcare services; access to social security), 9 (equality), 10 (human dignity and 22 (trade & professions);
(b) Compliance with the existing rights and structures and the powers of the provinces;
(c) Purporting to *not* be a Money Bill, but prescribing aspects of funding that should be included in such a Money Bill;
(d) The exclusion of other laws from the PNHIA.

The manner in which the PNHIA instructs other laws to be made, addressing specific matters and instructing that to be done in a particular way, seems to elevate the PNHIA to that of a constitution. It in effect removes, or at least severely curtails, the legislative power in relation to such other laws, and instructs not only how Parliament would have to exercise its legislative power in future, it also curtails the democratic processes, which should be able to influence the final form of any law. This, in itself, is an unconstitutional feature of the PNHIA.

On **point (a)**, we believe that the PNHIA, although recognising the concept of "social solidarity"[1], fails to find the constitutional roots of such a law in not only the right of access to healthcare services, but also in the right of access to social security. Social security law[2] aims to ensure that persons who may face social exclusion due to the occurrence of an event that are financially unmanageable, are covered.

[1] Included in the Preamble to the PNHIA, and a definition included in section 1
[2] See, for example, Olivier, MP in LAWSA "Social Security: Core Elements" (Volume 13(3) - Second Edition) and Olivier, MP "Social Security: Framework" (Volume 13(2) - Second Edition).

Social security mechanisms exist in relation to old age, ill health, accidents / injuries in workplaces or on the road, etc. Currently medical schemes, as well as the public health sector, provides some level of cover for the eventuality of ill health. What the PNHIA however does, it severely curtails social security rights, and in particular social insurance rights through the prohibition of obtaining cover benefits offered by the NHIF.[3]

Social security law should therefore underpin the PNHIA and the, still to be drafted, NHI Money Bill. Social security law is the mechanism through which access to healthcare services can be realised, progressively so. However, the PNHIA does not align with the principles of the Constitution and social security law and the right to access to healthcare (i.e. the whole of section 27) in that:

- It negates the constitutional criterion of "within its available resources" (section 27(2) of the Constitution). The lack of resources to implement the NHI has been made clear during the recent Medium-term Budget process, which states the estimates to roll out NHI that were published in the NHI Green Paper in 2011 and White Paper in 2017 are no longer affordable".[4] It also states that the PNHIA will cause an increase in healthcare spend of 4% of GDP to 5-6% of GDP. Even with the *limited* package (i.e. scrapping user fees, contracting GPs, etc.), a funding shortfall of R33bn is expected by 2026 (the envisaged *full* implementation date).[5]

- The re-organisation of the health sector, e.g. primary care structures (including contracting in the private sector), accreditation and licensing systems, etc. can (and indeed should) be done under the NHA, and there is no reasonable requirement that it be done under the PNHIA. As such, the PNHIA is not a "reasonable" legislative measure, as another measure already exists.

- It violates the principle of the purchaser – provider split. The purchaser in numerous places are actually occupied with regulating the provision of services,[6] dictating how such providers should be organised, etc. This should be the exclusive domain of the NDOH.

- Given that the latest reported priorities of the NHI, namely "contracting with private sector GPs, extending the chronic medicine distribution programme, expanding the HIV treatment programme, scrapping user fees at public hospitals, tackling medico-legal claims"[7] can all be done without the PNHIA, introducing legislation that is unnecessary will not pass constitutional muster, in particular if it would require additional costs. The law that should be given priority, should be amendments to the common law system of malpractice, and the related matters, such as record-keeping and the full implementation of the OHSC's functions. This will help to address the massive expense that is medico-legal cases, and without being addressed first, could lead to massive hardship in provinces being deprived from a substantial part of their Provincial Equitable Shares (PESs), being unable to honour malpractice debts.

In terms of **point (b)**, it is puzzling that the OSLA regards the matter as settled purely on the basis of the concurrent powers of the national- and provincial legislatures, and the matter of how to deal with conflicting laws. There is however more to this. There are existing provincial rights and functions being affected by this PNHIA in in various clauses, in spite of the "assurance" provided in section 3(4) that the Bill does not change any functions of any organs of state. However, that is exactly what is in various sections of the PNHIA.[8] It takes existing provincial functions, and the right to receive budgets for such

[3] Sections 6(o), 8(2) and 33.
[4] National Treasury *Medium Term Budget Policy Statement 2019*, 30 October 2019 available at: http://www.treasury.gov.za/documents/mtbps/2019/mtbps/FullMTBPS.pdf.
[5] https://www.businesslive.co.za/bd/national/health/2019-10-30-treasury-expects-nhi-funding-shortfall-to-rise-to-r50bn-by-2030/.
[6] Section 7(2)f, Section 57(4)a and others
[7] https://www.businesslive.co.za/bd/national/health/2019-10-30-treasury-expects-nhi-funding-shortfall-to-rise-to-r50bn-by-2030/.
[8] Section 7(2)(f)(iii) – central hospitals is semi-autonomous through powers delegated from the NDOH to them; section 32(2)(b) – tertiary and regional hospitals, currently under the provincial powers and functions now become accountable to the Minister of Health (it not actually being clear who the employer of such staff then would be) "through regulation"; section 32(2)(c) District Health Management Offices as "government components"

functions, away from provinces and place it with either the NDOH, the NHIF or even the Minister of Health! It also forces the transfer of staff from provincial employment to national employment, again with an impact not only on labour rights, but on the functions of the province. What is also odd is that the PNHIA instructs the reorganisation of the health sector in section 32(3) – if this indeed envisaged, surely one law cannot state that another law must be changed, both laws would need to be presented to Parliament so that the effect of such changes can be evaluated as coherent, rational and consistent, all of which are constitutional criteria.

The most glaring unconstitutionality is the inclusion of provisions relating to **emergency care**. Ambulance services is clearly an exclusive provincial competence (Constitution, schedule 5), and provinces would have to continue to receive funding (Constitution, section 227[9]) from the national fiscus (and not as a per event or otherwise (as of yet unknown) payment, from the NHIF) to render these ambulance services.

Lastly, the PNHIA purports, in its preamble, definitions and section 2(c) to be "**pooling (public) resources"** or **"-funds"**, but can, indeed does not do that. That pooling (i.e. removal of (part of) the PES from provinces, if indeed constitutionally possible, would only happen through the Money Bill.

It is also concerning that the PNHIA purports to not be a Money Bill (as per section 3(4)), but does exactly that in section 49 – it prescribes the income streams of the NHIF, including taxation, etc. As such it then does indeed become a Money Bill, which should be compliant with section 120 of the Constitution. There, also in this respect **point (c)**, the PNHIA is NOT constitutional, and it violates constitutional criteria.

To elaborate on the unconstitutionality referred to in **point (d)** above, the matter of conflicting laws and the exclusion of the Competition Act in section 3(3) and 3(5) is also concerning. The effect of this can be seen in the PNHIA itself – there is a selective application of the POPIA in section 6(m), whilst section 34(2) seems to recognise the full application of the POPIA, but POPIA only has to be "considered" when submitting information to the NHIF. POPIA, PAIA and PEPUDA, all mentioned in the PNHIA apply and should apply to its full extent to the decision-makers and implementers acting under the PNHIA, the PNHIA should not be a harbour against such full application of those laws. These laws, together with the Children's Act, 2005 and Promotion of Administrative Justice Act, 2000, should apply without hold or barrier, to the NHI system.

Competition Commissioner Bonakele, on 30 September 2019, during the launch of the final report of the HMI, made it clear that the **Competition Commission does not condone the exclusion of the Competition Act** from the ambit of the PNHIA and regards it as a mistake. The HMI is proposing a system of collective bargaining which, if implemented, will obviate the necessity for such a drastic step. This exclusion, as proposed in section 3(5) of the PNHIA, is overbroad in constitutional terms and will allow abuse of dominance, piece discrimination, etc., as well as collusive tendering, under the NHIF system. Significantly, and contradictory to this general exclusion, the PNHIA then in section 39(7) refers to the Constitution's section 217, that requires of procurement to be "fair, equitable, transparent, competitive and cost-effective". If the Competition Act is excluded, who will the competitiveness of procurement processes be judged? Or, if the intention is to revert to competition common law – does it mean that South Africa will in health, have two sets of competition law principles apply -the Competition Act to non-NHI matters, and competition common law to NHI-matters?

2.2. Health sector reforms: policy coherence

Health sector reforms should be coherent, and such coherence should be evident from the various policy- and legislative reforms. A number of health sector transformational processes appear to not have affected the development of- and introduction of the PNHIA into Parliament, and creating overlaps, as

[9] ***227. National sources of provincial and local government funding.****—(1) Local government and each province— (a) is entitled to an equitable share of revenue raised nationally to enable it to provide basic services and perform the functions allocated to it.*

well as potential contradictory legal- and implementation frameworks, that will introduce legal uncertainty and risk of legal challenge. These are:

- **Accreditation** (by certification) of suppliers and providers by the NHIF. Accreditation functions are already awarded to the NDOH (Director-General) under section 36 NHA; the HPCSA, SAPC and SANC for most healthcare professionals; SAHPRA for all medicines, medical devices and IVDs; NDOH on permits for human tissue provision; SANAS for laboratories, etc. Whereas all of the bodies, in their empowering legislation, clearly set out the criteria for the accreditation, there are no clarifications listed in the PNHIA's section 39:

    - Which criteria that could mostly only be assessed *ex post facto* and not before services are provided and hence before accreditation, such as rendering services at the "appropriate level of care" according to users who are "in need" and "entitled to the benefits", "adherence to treatment protocols" and the formulary, "submission of information", "adherence to referral pathways" and "adherence to the national pricing regimen" (sic). The reference to "needs" bring this within the same regulatory ambit as the Certificate of Need (CON), already governed under the NHA.
    - It also requires proof of OHSC certification (which assumes that the OHSC would be able to inspect every one of the more than 14 951[10] medical practices with practice numbers), statutory council registration, offer the "required range of services", the "appropriate number and mix of healthcare professionals". Also, these criteria overlap significantly with those found in sections 36 and 39 of the NHA;
    - This will be reviewed every five years, whereas the CON would require a duration of a maximum of 10 years, which appears to indicate that the NDOH is not clear on what it would deem to be an appropriate period for this type of accreditation / certification. As with the CON, rights to withdraw an accreditation / certification is also permitted.

- The CMS is working on a review of the **PMBs to include PHC benefits**, which, by change to the PMB Regulations, would have to be legislated and implemented, within the next years. The PNHIA's sections 6(o) and 33 make it clear that medical schemes would not be permitted to cover services covered by the NHIF. This makes the massive effort being undertaken to expand the PMBs, and then ensure its financial modelling, legislation thereof, and implementation, fairly futile, as it would be applicable at most for only a few years. The PNHIA in section 57(2)(4)(f) makes it clear that PHC will be covered by the NHIF as part of phase 1 (2017 – 2019 (sic.)).

- Suppliers are to be accredited according to regulations to be issued under section 55(1)(h) of the PNHIA. However, licensing of suppliers of medicines, medical devices and IVDs are done by **SAHPRA**, according to the Medicines and Related Substances Act, 1965. It is unclear what will happen if SAHPRA licences a supplier as one that supplies products of good quality, that is efficacious or perform as intended, and are safe, but the NHIF does not accredit, according to as of yet unknown criteria and for unknown purposes.

2.3. The Health Market Inquiry (HMI)[11]

The findings of the HMI and its recommendations are significant. Indications that these will be implemented, are good, and these recommendations have been reported in the media as necessary to lay the foundations for the private sector being suitably re-organised to participate in the NHI. However, both in terms of timelines and content, the PNHIA and the HMI recommendations are in conflict.

[10] Health Market Inquiry *Final Findings and Recommendations Report* September 2019, page 135.

[11] Health Market Inquiry *Final Findings and Recommendations Report* September 2019, available at http://www.compcom.co.za/wp-content/uploads/2014/09/Health-Market-Inquiry-Report.pdf.

For example, in terms of provisions on **content**, there are the following contradictions between the HMI and the PNHIA:

The PNHIA stipulates that **prices will be set / determined** in terms of section or negotiated by the NHIF – as the "lowest possible price" under section 11(2)(e))and then not only for services, but also for "benefits" (recommended by the Benefits Pricing Committee in terms of section 26(3) and by the NHIF's Board to the Minister in terms of section 15(3)(c), who, so it appears, would then set prices in terms of section 55, which will set the "national pricing regimen" (sic.) to which accredited providers must adhere (section 39(2)(b)(vi)). Payment will be determined through regulations under section 55(1)(b), and as referred to in section 41. Although the PNHIA is contradictory as to exactly who will determine the "national pricing regimen" or who will negotiate the "lowest prices" (the Board, the NHIF, the BPC and/or the MOH), the intention is clear – the NHIF will set the prices or payment for the services rendered by healthcare to the NHIF.

In contrast, the HMI recommends a system of **price negotiations**,[12] to set maximum price levels for certain benefits (such as a new basic benefit package that would include PHC), with bilateral negotiations possible with funders (which would include the NHIF) on value-based contracting and other alternative reimbursement models. The HMI recommended that, in the interim, the NHA's provisions on a reference price list could be implemented quite easily, provided, of course, that the guidance on compliance with the principles of administrative justice and lawfulness, as found in the so-called RPL case,[13] are followed.

HealthMan and its members **prefer negotiated prices** above those unilaterally set, in particular if there are no criteria (as is in the NHA) in accordance to which regulations will be made, or according to which such prices be determined.

The HMI also proposes that the activity of licensing (of, amongst others, hospitals) be a national function (this is currently a provincial function), to be exercised by the Supply Side Regulator for Health (SSRH).

Also in. terms of coding, and healthcare value assessments, the recommendations by the HMI and the PNHIA are diametrically opposed.

On coding, the PNHIA mandates "diagnostic and procedure **codes**" to be used (section 39(5)), and to be submitted in terms of regulations (section 55(1)(e)), and alludes to the necessary implementation of ICD10 coding, to get to the DRGs referred to in section 35(2). The HMI proposes that coding be removed from any specific stakeholder, in order to avoid and correct the issues it identified during its investigation, and be a function of the SSRH. HealthMan supports this move, as no funder, whether the NHIF, or a medical scheme, should determine what the correct and appropriate codes are to describe healthcare activities (diagnostic, procedural or otherwise).

On **value assessments**, the HMI also proposes this function to be based outside of any funder or regulator with a stake or an interest in its outcomes (e.g. the NDOH will have a stake in medicines pricing, as the regulator thereof), proposing it also be housed in the SSRH. The PNHIA determines that the NHIF will not fund "an intervention" if it is not "cost-effective" as determined by a "health technology assessment" (HTA). It is not clear from the PNHIA who will do these "health technology assessment" (section 7(4)(b)) and no legislative framework exists or are being proposed for these assessments. In section 57(3)(d) reference is made to a Ministerial Advisory Committee on HTA. However, nowhere in the PNHIA (also not in the regulations) or any other legislation is any other or further provision made for this Committee to become the "HTA Agency" referred to in section 57 of the PNHIA.

[12] This system can be summarized as follows: The HMI recommendation for the SSRH to set a maximum PMB tariff and a reference tariff for non-PMBs. Bi-lateral negotiations on ARMs (such as value-based contracts) would also be possible (to be submitted to the CMS and SSRH for approval) and may vary from the general tariffs negotiated (for full description see HMI Report at chapter 7 (page 178ff).

[13] Hospital Association of South Africa Ltd v Minister of Health and Another, ER24 EMS (Proprietary) Limited and Another v Minister of Health and Another, South African Private Practitioners Forum and Others v Director-General of Health and Others [2011] 1 All SA 47 (GNP) (28 July 2010).

The HMI points to the necessity to have the **SSRH be independent** from funders and service providers, and references both the **UK and Thailand** as examples where such separation does exist.

And, for example, in terms of **timelines**, there are the following contradictions between the HMI and the PNHIA:

The SSRH will take **at least five years to establish**,[14] as it would have to be set by legislation, i.e. by **2025**. The NHI is to be fully implemented by **2026**. If it is true that health policymakers and the managers of the NHI process see the HMI as a necessary precursor, the effort of establishing it, and then only having it in effect for a year prior to the PNHIA coming into full force and effect, seems irrational.

2.4. Funding reforms: the MTBPS, 2019, the Funding Paper and the DTC

The Funding Paper for the NHI, promised in August 2019, has not yet been seen. Not only does the benefits, payment thereof, and the availability of medicines, devices and IVDs depend on the financials of the NHI, also its administration, and the costs of the biometric system, the cost of HTA, the various advisory Committees, Board, staff and other operational items which are yet to be costed. The cost of transfer of staff from being provincial employees, to the NDOH, i.e. compliance with the Labour Relations and Public Service Acts, must be costed. Most recent experience with SAHPRA has shown that it was impossible to meet legislated timelines in transferring staff from the NDOH to SAHPRA (which did not even involve movement from provincial employment with differences in conditions of employment). This will be more complex where central facilities are concerned, as not only employment transfers, but also multilateral agreements involving provinces, universities and other third parties (e.g. private hospitals) may be at stake.

The only information on the funding model currently available, is the 2019 Medium-Term Budget Policy Statement (**MTBPS**), which highlights the much slower pace of implementation of the NHI, very similar to how it is being done currently, through direct and indirect grants to the provinces. None of the envisaged aspects listed to be implemented in a media interview[15] requires the PNHIA.

It is noteworthy that even before the PNHIA was introduced as a draft Bill in 2018, or now as a Bill, and before the 2017 NHI White paper publication, the **Davis Tax Committee** (DTC), in its report on the NHI,[16] cautioned (page 43-44):

- "*Should the real annual growth rate reach just 2%, then the **shortfall could be as large as R108 billion**. Should the average growth rate dip below 2% (as is currently the case), then it is likely that even the R108 billion figure could substantially understate the actual shortfall*". It was announced in the MTBPS that growth will be at only 0,5%, i.e. a quarter of that envisaged when the NHI White Papers were completed. The shortfall projected by the DTC is significantly higher than that projected by the National Treasury of R55 billion.
- "*As NHI entitlement will result in a structural increase in spending, additional public expenditure should be financed by tax instruments which are sufficiently buoyant to yield a structural increase in revenues of the appropriate magnitude*." It does not seem that, given the current economic climate, revenues of such magnitude could be reached.
- "*Equally important are the **behavioural responses** of members of private sector medical aids and their perceptions of the quality of services they receive under the NHI. The highest earners are also the most internationally mobile.*" The DTC warns of the potential of a tax revolt, similar to what has been experienced with e-Tolls.

[14] HMI, page 213.
[15] https://www.businesslive.co.za/bd/national/health/2019-10-30-treasury-expects-nhi-funding-shortfall-to-rise-to-r50bn-by-2030/.
[16] https://www.taxcom.org.za/docs/20171113%20Financing%20a%20NHI%20for%20SA%20-%20on%20website.pdf.

The DTC then concludes:

> *"Given the current costing parameters outlined in the White Paper,* ***the proposed NHI****, in its current format,* ***is unlikely to be sustainable*** *unless there is sustained economic growth."*

Neither is the **OHSC adequately capacitated** for its envisaged role in the PNHIA, it does not have adequate funding to inspect and certify all health facilities. Indeed, it reported to the Health Portfolio Committee in Parliament on 4 September 2019 that the 5.5% budget increase is not enough.[17] Where the OHSC has undertaken inspections, the non-compliance of most public health facilities are well-documented. To be rational and reasonable, any PNHIA should be dependent on doing "first things first", including considering the timelines required for (a) all inspections and (b) the necessary quality improvements. If not done, the legislative prohibition on contracting due to inability to comply with the legislated OHSC certification, will lead to public health facility being substantially unfunded, bringing already vulnerable institutions to collapse.

Simply put, from a financial and practical perspective, the NHI system is far from ready to be legislated, and any rush to do so, is purely political. It will only raise the expectations of the public, and could lead to grave disappointment and action by an aggrieved public. This reinforces the HealthMan's view that the PNHIA is not practical, implementable and the system is not ready to be legislated. Most of the envisaged reforms, whether the reorganisation of the health sector, the expansion of access, free at point or the implementation of the HMI does not require the PNHIA, and only requires implementation of existing legislation and policy.

2.5. The role of the NDOH versus that of the NHIF

It seems that the PNHIA would be a "second change" for the redesign of the health system. Again, such redesign, being based at the supply / provider side should be based at the NDOH and MOH, and not at the PNHIA. The NHIF, and its various structures, should not be involved in regulating the provider / supply side. As it stands, the PNHIA violates its own principle as stated in Section 7(2)f, Section 57(4)a and others.

The PNHIA should be a law that deals with how monies are to be spent in order to achieve social security objectives in health. It should be accompanied by the elusive Money Bill, as well as the amendments to the NHA, and various sets of healthcare professional legislative reforms – inadequate or not addressed at all in the current table of amendments (some not within the jurisdiction of the NDOH to recommend). None of this has been done, and the absence of these pieces of companion legislation again confirms the state of unreadiness of this law to be put to Parliament.

Absolutely vital provisions in the NHA, for the successful rollout of the NHI, remain, sadly so, unimplemented. This includes, amongst others:

(a) The Human Resource strategy and principles, without which access to healthcare cannot be delivered (NHA, section 48 and section 52, which requires regulations on important matters such as education and training; planning, recruitment and retention; roles and functions of PDOHs and the NDOH, etc,). The often-cited complaint by the previous MOH that he had no control over PDOHs in terms of human resources is therefore, not correct.

(b) The numerous provisions on the health information system and record-keeping, part of which is also necessary to address the medico-legal challenge (NHA, sections 13, 15 – 18, 73 – 76).

(c) Section 50, the Forum of Statutory Health Councils, without which the reorganised PHC system and the CUPs, cannot be implemented, do to, for example, the prohibition in the Pharmacy Act on healthcare practices of prescribers being situated in, or as part of, a single entity where a pharmacy

[17] https://pmg.org.za/committee-meeting/28823/; https://www.businesslive.co.za/bd/national/health/2019-09-04-health-facility-watchdog-calls-for-more-funds/.

is also present, or the sharing of fees as is envisaged by the PNHIA in section 41, that hospitals and specialists will be paid an "all-inclusive fee".

The failure to implement the above will severely hamper the implementation of the NHI, and if passed in its current format, will lead to legal challenges or even prosecutions for violations of other laws, such as the Pharmacy- or Health Professions Acts.

2.6. The unspoken impact of the medico-legal burden on the PNHIA

Although the National Treasury has prioritised dealing with medico-legal claims, the **PNHIA itself is silent** on exactly what the implications of **medico-legal liability** would be on the NHIF. This includes:

- Existing medico-legal liabilities of provinces: will this debt also be pooled, or only the PES, and if the debt stays in the province, how will PDOHs cover those costs in the absence of the PES, and with only allocations to cover staffing? These liabilities are significant (e.g. in 2017 it was, in value, the same as all ten central hospitals' budgets together,[18] with latest estimates more than double, i.e. at R98 billion[19]), and as cases involving children could be lodged up until they are 21 years old, the claims that could still reach provinces on past matters, are unknown. Addressing this issue will therefore also free up significant amounts of money to enhance service delivery in the public sector.
- Who would carry legal liability for the private practitioners or facilities that are either contracted to the NHIF, or that form part of the CUPs? Such persons or entities are not protected by the State Liability Act and current indemnity providers do not cover private sector HCPs working in the public sector.
- Furthermore, if the cause of the harm lies with the NHIF's rules and requirements (e.g. the enforcement of a referral pathway, or the absence of a medicine from a formulary), the NHIF, and not the specific HCP should bear legally liability. Has this, and if so, to what extent has this been factored into the PNHIA planning and budgeting?
- The provisions of section 46 of the NHA have not been implemented, and, although oddly worded, this should have ensured that all healthcare professionals are subject to some form of liability cover. Section 46 however, only applies to the private sector and not the envisaged NHI system, or private providers working in the public sector or contracted to a publicly-funded sector.

The elephant in the medico-legal room, is, however, the **inappropriateness of the legal rules** in terms of which liability, and the corresponding compensation payable, is established. Without addressing this, along the lines as proposed by the SA Law Reform Commission as long ago as May 2017,[20] no amount of budgeting, training, quality improvements and other reforms will address its root cause and the massive implications on the NHIF in the future.

HealthMan urge the immediate finalisation of the SALRC's project, and the implementation of the necessary steps to address deficiencies in malpractice law, not only to ensure the existing and future viability of the health system, but also to insulate the NHIF from being targeted by personal injury lawyers, as is the case with provincial health departments at present.

3. The PNHIA, section by section

In the commentary below, the text of the PNHIA is copied in blue font:

3.1. Preamble

The preamble reads:

"… within its available resources …

[18] In the year 2017/8 the malpractice liability was, nationally, at R43 billion (https://www.iol.co.za/capetimes/news/state-in-r43bn-medical-claims-8360883), compared to the central hospital budgets for that year of R39,5 billion.
[19] https://www.fanews.co.za/article/healthcare/6/general/1124/will-nhi-worsen-sa-s-medico-legal-nightmare/27522.
[20] http://www.justice.gov.za/salrc/ipapers/ip33_prj141_Medico-legal.pdf.

AND IN ORDER TO—
- achieve the progressive realisation of the right of access to quality personal health care services;
- make progress towards achieving Universal Health Coverage…

Comment: The fact that the PNHIA is published in order to "achieve sustainable and affordable universal access to quality health care services", without any costing of the model having been published in the 10 years since the inception of the scheme, is disingenuous at best and a gross failure of due diligence at worst. It is a requirement of the Constitution, and itself. Quoted in the preamble, that the "available resources" would need to be indeed "available" and such availability would need to be demonstrated for the PNHIA to be constitutional and in line with section 27 on health, and on social security.

It is concerning that attempts are being made to implement NHI without the government providing any clarity on what the initiative might cost and how it will be funded in the current economic climate. Although political success stories of the NHI have dominated in the public discourse, case studies of failures, such as that in Ireland, and not often raised. The costing of the model proved unaffordable for Ireland "now or ever" and the Irish NHI was scrapped, with alternatives now being considered[21].

Implementing this NHI model in an environment which is not able to afford a very comprehensive NHI service basket, will lead to the majority of South Africans having access to less comprehensive health services than is currently the case in both the public and private sectors. This would not be the "progressive realisation of healthcare" that is demanded by section 27(2) of the Constitution, as quoted in the PNHIA preamble.

3.2. Definitions

"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*

Comment: This definition will be a moving target, as, in the words of the Registrar of the CMS, "as benefits are added to the NHI, it will be taken away from medical scheme benefits. According to this definition, a Private provider who does not contract with the NHI Fund will render personal healthcare services not reimbursed by the Fund. This would therefore mean that services by such a provider would qualify for reimbursement as "complementary cover." However, section 33 appears to state the converse, namely that non-NHI funders (medical schemes and to the extent that they are so exempted, other health insurance products) may NOT reimburse what would be set as NHI benefits.

"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.*

Comment: The Deputy Director General of NHI, Dr Anban Pillay said "the cover the government will provide will be determined by the economy, **which dictates what the state can afford**". He said "when the economy does badly, this would affect the budget allocation, which may impact on the services that will be covered. This will then impact on the services that schemes will cover as complementary cover." This, together with the MTBPS and the interview with Mr Blecher of the National Treasury on the "limited set of interventions", is the clearest indication that the Government will reduce the service basket based on the available budget. Notwithstanding, the PNHIA, however, **promises "comprehensive care"**

[21] https://www.irishtimes.com/opinion/editorial/an-outstanding-policy-failure-on-universal-health-insurance-1.2439791

repeatedly,[22] and also indicate that care at various levels will be contracted by the NHIF. There are no direct provisions relating to the staggering or, in constitutional terms, the progressive realisation of healthcare by means of benefits, save for what is stated in section 57(4)(g)(ii) on "purchasing hospital services and … , which must be "an expansion of the … services purchased".

The effect of the unqualified legislative promise is that any user could force the NHIF, by *mandamus* or otherwise, to implement this legislative promise of a "comprehensive package", and the NHIF could not rely on section 36, as the law that could limit access to healthcare, namely the PNHIA, does not provide for such limitation in a manner that would speak to being reasonable, fair and justifiable.

In spite of the progressive nature required when health rights are to be realised, the reality however is that, if members of public currently using the state have access to a smaller basket of services than currently available in the state, it is ***regressive* in nature**. There is also the aspect of medical scheme members who could see medicines that are currently funded by medical schemes not being funded in NHI and whether this is progressive realisation of access to healthcare.

There is also no proposed amendment to section 4 of the NHA, which currently gives only limited rights to free healthcare, and then only when such free healthcare is obtained from public health establishments.

"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;*

"hospital" *means a health establishment which is classified as a hospital by the Minister in terms of section 35 of the National Health Act*

Comment: The above definitions are nor clear, and even where applied in the PNHIA, are inconsistently phrased. Providers (which seems to refer to what is defined in the NHA as "health care providers", is sometimes denoted by the above definition of "health care service provider", but sometimes referred to only as "providers",[23] "private providers",[24] "service providers"[25] or "health care provider",[26] none of which are defined, and may, or may not mean the same. It is suggested that the definitions in the NHA be used, as that is the law that organises the structure of the health sector, as the provider-part of the purchaser-provider split.

Although the "provider" definition is not aligned to the NHA's, the "health establishment" definition[27] is. Under the NHA a health establishment is a place, or part of a place, where health care services are rendered, and providers are registered healthcare professionals that work in such establishments, or may own, or part-own it. It could, for example, be the place where a nurse practitioner working in- and being employed by a pharmacy, is working in that pharmacy, the space used by an educational psychologist working in a school, a public sector district hospital where various providers work, etc. The definitions above do not form a logical and coherent system as per the NHA, and as aligned to healthcare professional legislation. It is proposed that only the term "health establishment", as denoting public or private places where NHI users could access care, are provided, be used in the PNHIA, as the law governing the purchaser should not be stipulating new definitions of providers.

---

[22] As part of the definition of "strategic purchasing"; section 15(3)(b); section 32 (1)(c) and section 38(8)(a). It should also be noted that in the Memorandum to the Bill, at paragraph 4.2 PHC is stated to be delivered in "comprehensive way" and that the BAC would have to determine the "comprehensive cover" the NHIF would have to purchase.

[23] Definitions of "provider payment" and "strategic purchasing … contracted providers"; section 11(1)(h)(iv); section 20(3)(c) and (f); section 27; section 41(1) and (5); section 47(4)(f);

[24] Section 37(2).

[25] Heading to section 39 and in the text thereof; section 40.

[26] Section 6(a).

[27] Section 1, NHA: *"health establishment" means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services.*

The *de facto* introduction of the CON, applicable to all health establishments, as per sections 36 – 40 of the NHA, but now through the PNHIA as "accreditation", remains a concern for HealthMan.

The types of service providers not included in these definitions or in the PNHIA, is the SA blood services, entities such as tissue banks, etc. It is recommended that the definitions related to the blood, tissue, and organs be adopted from the NHA and the associated sets of regulations of 2 March 2012, where it is necessary to define such entities as service providers to the NHIF.

"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*

Comment: The PNHIA disregards important distinctions made in other legislation and in doing so, inappropriately regard a wide range of products as being "similar" or subject to similar treatment under the PNHIA's access and procurement provisions. Products can be classified as follows:

Products used before, during and/or after the treatment of patients, and includes:

(a) Medicines, medical devices and IVDs, with medical devices including equipment, and already defined in, and governed under the Medicines Act;
(b) Blood, blood products, and human tissue, already defined and governed in the sets of regulations issued under Chapter 8 of the NHA, which products are used, but not sold (although the services associated with its provision are);
(c) Hazardous substances, which includes consumables and injectables and equipment, defined by, and governed by the Hazardous Substances Act;
(d) Food for special medical purposes, governed by the Foodstuffs, Cosmetics and Disinfectants Act (FCDA), including infant feeds.

There are also products used not to treat, but to create the environment within which to treat, such as furniture (excluding those defined as medical devices, such as theatre lights), vehicles, fixtures (lights, air-conditioning, etc.), food, linen, IT infrastructure and the likes. Some disinfectants, for example, fall within the Medicines Act as medical devices, and some under the FDCA, with some regulation under the NRCS. The criteria for procurement and supply are vastly different, and lumping all of these together is problematic, also as some aspects of it, such as those that would stay in a public health facility in a province, will be unaffected by the PNHIA, so will capital expenditure (medical devices or otherwise) already in the private sector.

Although some references have been made in the media on the inclusion of traditional medicine in the NHI, these, and complementary and alternative medicines (CAMS) remain largely unregulated. CAMS, at least, are part of the wider definition of "medicine".

There are also many phrases and words in the PNHIA that **are not defined**, such as "personal-" and "non-personal health services";[28], the meaning and inconsistent use of "autonomous" as opposed to "semi-autonomous" in relation to hospitals,[29] etc.

[28] In the definition of "complementary cover", sections 32(2)(c), -36, -39(2)(b)(i), -40(3)(b) and (f), -55(1)(l), 57(2)(a)(iv), -57(4)(f) and (g)(ii), and the amendments proposed to the Medical Schemes Act.
[29] Sections 7(2)(f)(iii), -32(2)(b), -57(4)(a) and in the memorandum to the Bill, paragraphs 4.10 and 4.11.

3.3. Section 2: Purpose

"The purpose of this Act is to establish and maintain a National Health Insurance Fund in the Republic funded through mandatory prepayment … single purchaser and single payer … ensuring the sustainability of funding … by pooling of funds and strategic purchasing"

As stated above, the PNHIA is not a Money Bill, and can therefore not govern the funding "through mandatory pre-payment" neither can the NHIF "pool" any funds, or ensure "sustainability of funding". It can at most set itself up as a purchaser and payer, and ensure these activities take place "in a sustainable manner".

3.4. Section 3: Application

(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.

Apart from the issue raised above at 2.1 (d), relating to the constitutionality of this section in the PNHIA, this section makes the PNHIA unacceptably overpowering in the healthcare sphere, and even beyond. It would supersede the Children's Act, the POPI Act (although the PNHIA contains contradictory sections in this regard, e.g. section 40(4)(c) contains its own list of justifiable disclosures, at odds with POPIA), the Consumer Protection Act, the Health Professions Act, Medical Schemes Act and even the Health Act itself. This could have a radical impact on consumer rights in this environment, but could also affect the way the healthcare professionals are expected to keep to ethical medical practice in such an environment. In cases of conflicts between ethical rules, such as the duty to obtain informed consent (which includes being informed about treatment options, also those not available as part of the NHI benefit package, and the provisions of the PNHIA, last-mentioned will override these ethical and legal obligations. This clause is likely to impinge severely on patient rights. If a practitioner acts in an unethical manner due to a system design issue in NHI, the patient will not have any recourse to lay a complaint for such behaviour with the HPCSA. With the amount of discretion the Minister of Health has in publishing regulations in the NHI Fund, this clause is extremely concerning from a governance perspective.

The drafters, and the OSLA appear to have missed that, instead of inserting a general override, other laws would only not find application if the exemption mechanisms in such laws are being followed. This applies to the Consumer Protection Act, 2008,[30] and the Competition Act, 1998.[31]

The conflict of laws provision would also affect that the existing collective agreements between trade unions and the public service, most notably PSCBC Resolution 1 of 2006, which established the Government Employees Medical Scheme would be supplanted by this Bill. These collective agreements, as defined in section 213 of the Labour Relations Act, cannot be varied, amended or rescinded in the same way that legislation is amended. This may lead to labour unrest and industrial action on a massive scale in the public sector.

(5) The Competition Act, 1998 (Act No. 89 of 1998), is not applicable to any transactions concluded in terms of this Act.

---

[30] Section 5(3): *"A regulatory authority may apply to the Minister for an industry-wide exemption from one or more provisions of this Act on the grounds that those provisions overlap or duplicate a regulatory scheme administered by that regulatory authority in terms of—*
(a) any other national legislation; or
(b) any treaty, international law, convention or protocol.
(4) The Minister, by notice in the Gazette after receiving the advice of the Commission, may grant an exemption contemplated in subsection (3)—
(a) only to the extent that the relevant regulatory scheme ensures the achievement of the purposes of this Act at least as well as the provisions of this Act; and
(b) subject to any limits or conditions necessary to ensure the achievement of the purposes of this Act."

[31] Sections 3(3) and 10.

Competition law scholars and even the Competition Commission is in agreement that this exclusion of the Competition Act is unwise and would have severe, unintended consequences. Apart from not considering the HMI findings that were available at the time of drafting the PNHIA, it seems to adopt a rudimentary understanding of competition law, namely that to set tariffs, and to do so in collective consultation, the total and absolute exclusion of the Competition Act is required. This understanding of the Competition Act, and competition law, is wrong.

3.5. Section 4: Population coverage

(1) The Fund, in consultation with the Minister … on behalf of … (a) South African citizens; (b) permanent residents; (c) refugees; (d) inmates …; (e) certain categories or individual foreigners …
(2) An asylum seeker or illegal foreigner ... emergency services … notifiable conditions …
(3) All children, including children of asylum seekers or illegal migrants, are entitled to basic health care services …
(4) A person … must be registered as a user of the Fund …
(5) A foreigner visiting the Republic…

Section 27(1)(a) of the Constitution dictates that "***everyone*** has the right to have access to health care services, including reproductive health care. Although case law has established the rights of the non-citizens listed in section 4(1), in terms of access to social assistance and employment, the exclusion and limitation of rights of the persons listed in sections 4(2) and (5) from access to healthcare services will be different. The exclusion of certain people who are present in South Africa through illegal means might not pass Constitutional muster. This is as health care rights are different to social assistance rights – there are aspects of human dignity and wellbeing involved, different to social grants. Will the NHIF exclude a pregnant woman about to give birth, a person living with HIV (HIV is not a notifiable condition, TB is) from cover? If so, what are the public health implications of this, e.g. an emergency because of the unattended birth or the untreated person living with HIV infecting others? Even where entitled under the PNHIA, asylum seekers and Illegal foreigners may encounter difficulties as they would not be registered as users on the NHI system. The same would apply to visitors to South Africa – will visitors who do not require visas be turned away at SA borders if they are not in possession of health insurance?

There would also have to be a separate service basket for children of foreigners, which contains the basic health care services referred to in 4(3) and an indication that they only qualify for this basket. This is already creating different tiers of access to services in the NHI, which would be an administrative problem. The provisions of section 4 of the NHA would also have to be amended, as it only mandates limited cover for children.

It would in any event be untenable for NHA and PNHIA to have contradictory provisions, if the MOH can declare certain care free of charge in the public sector only under the NHA's section 4,[32] but the PNHIA provides that all care it funds, would be free,[33] whether obtained in the public or private sector. The

[32] ***4. Eligibility for free health services in public health establishments.***—*(1) The Minister, after consultation with the Minister of Finance, may prescribe conditions subject to which categories of persons are eligible for such free health services at public health establishments as may be prescribed(2) In prescribing any condition contemplated in subsection (1), the Minister must have regard to—*
(a) the range of free health services currently available;
(b) the categories of persons already receiving free health services;
(c) the impact of any such condition on access to health services; and
(d) the needs of vulnerable groups such as women, children, older persons and persons with disabilities.
(3) Subject to any condition prescribed by the Minister, the State and clinics and community health centres funded by the State must provide—
(a) pregnant and lactating women and children below the age of six years, who are not members or beneficiaries of medical aid schemes, with free health services;
(b) all persons, except members of medical aid schemes and their dependants and persons receiving compensation for compensable occupational diseases, with free primary health care services; and
(c) women, subject to the Choice on Termination of Pregnancy Act, 1996 (Act No. 92 of 1996), free termination of pregnancy services.
[33] Preamble, sections 6(a) and 8(1).

scrapping of user fees, as indicated by the National Treasury in the week of the MTBPS, would mean that section 4 is effectively amended.

This section does not expressly state, as the Constitution does, that all persons have an absolute right to emergency medical treatment. In addition, if a person who is properly registered but is, for some reason unable to produce proof of such registration, would such person be turned away in emergency situations?

As with other places in the PNHIA, the NHIF sets the benefits "in consultation with" the MOH. This means that the MOH has an effective veto on the benefits. It would also seriously undermine the independence and clinically sound nature of the NHIF and the BAC, if these bodies have to consult the political leadership on these matters.

3.6. Section 5: Registration of users

(1) A person… must register as a user with the Fund at an accredited health care service provider or health establishment.
(2) … must register his or her child as a user with the Fund… [and] A child born to a user must be regarded as having been registered automatically
(3) A person between 12 and 18 years of age may apply for registration as a user if he or she is not registered …
(4) … Children's Act…
(5) … biometrics
(6) … foreign nationals …
(7) Unaccredited … establishments… maintain a register of all users

The use of the word "must" in section 5(1) means that **no person**, who would be eligible, e.g. citizens and permanent residents **may opt out of registration** with the NHIF.

The registration must take place "at an accredited health care service provider or health establishment". This means that all accredited providers would have to have access to the equipment required to complete this registration process (including biometrics, e.g. to scan and upload fingerprints and to scan and upload photographs). Apart from this, reception staff at practices would be required to facilitate these registrations. It is unclear whether practices will be supplied with the equipment or whether they will have to purchase such equipment. Every practice (and health establishment, e.g. a remote rural clinic or a rural GP practice) will also require an active internet connection of adequate capacity to fulfil these functions.

In terms of section 5(7), all **unaccredited** health *establishments*, but not unaccredited health care service providers, would have to "**maintain a register of users**". It is not clear who will bear the costs of keeping such registers at unaccredited establishments. This is an overbroad and unauthorised power, and if the MOH wanted to prescribe the record-keeping of non-NHI-associated establishments, s/he has to do so by means of regulations issued under the relevant provisions of the NHA. The PNHIA can only apply to the NHI, and not govern matters outside of it. Now section 5(7) gives the MOH the power to determine what must be entered into this register, with no provisions as to what its purpose is, who will access this register, and under which circumstances, etc. This not only violates the POPIA, but also the Constitution.

It has already been reported that the NDOH has already compiled a "Health Patient Register System (**HPRS**) … *for 73% of the population and was moving towards getting the total population recorded. It was also digitising health patients' records to reduce their waiting time."*[34] And, that as part of the NHI Pilot Sites there is "an online registry of all patients using healthcare services in South Africa that can be

1. [34] Portfolio Committee of Health, *DoH, NHLS & SAHPRA 2018/19 Annual Reports; with Minister & Deputy Minister* 15 October 2019, minutes from PMG available at: https://pmg.org.za/committee-meeting/29073/.

accessed at any facility to provide health workers…".[35] The HPRS, developed in partnership with the CSIR, uses one's identification document as the unique identity verifier. It was reported that as at 31 March 2019, 2 955 PHC facilities and an additional six hospitals were implementing the HPRS. It is also unclear how a database of 73% of the population could be set up, if the system is mostly only including PHC facilities at this stage?

It is unclear what the **legal mandate for setting up this HPRS is**, given that the PNHIA is not yet law, and that no regulations have been published under section 74(2) of the NHA, nor under section 90(1)(t) to authorise the collection of such personal information, its inclusion and processing into a national database. As a limitation to the constitutional right to privacy such a database must be authorised by a law that passes the tests set by section 36 of the Constitution. This does not appear to have happened, and, again, shows how the implementation of the NHI is not being done in a proper, legal manner. **Regulations under section 74 should have preceded this**.

The registration of children is also not clear – it seems that one of the child's parents must do this, which raises the question as to how the child would be linked to the other parent? Or, as **caregivers** have rights to give consent to the treatment of children under the Children's Act, 2005, why a child could not be registered by such a caregiver, given the large number of children being cared for by grandmothers or other relatives in South Africa? Also, given the HPRS, how are these linkages currently being made?

As with my other sections in the PNHIA, the MOH has unfettered discretion in section 5(6) to set criteria for the registration of foreign nationals – the empowering Act, the PNHIA, gives no indication as to what is envisaged here, and is therefore an unauthorised delegation of legislative powers.

3.7. Section 6: Rights of users

Without derogating from any other right or entitlement … 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…
(b) … information … benefits ..
(c)… information or records … as provided for in the Promotion of Access to Information Act,
(d) not to be refused access to health care services on unreasonable grounds
(e) not to be unfairly discriminated against …
(f) to access … within a reasonable time …
(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 …
(j) to request written reasons …
(k) to lodge an appeal …
(l) to institute proceedings …
(m) to the protection of his or her rights to privacy and confidentiality …
(n) to have access to information on the funding …
(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…

"Without derogating…"
Section 6 in its introductory phrase "without derogating from any other right … under any other law" (saying the wording does not and should not conflict with existing rights) is in conflict with section 3(3) (saying where it does derogate, i.e. conflict, the PNHIA will override). This creates the bizarre situation that

[35] Parliamentary question to, and answer by the MOH, 14 October 2019 [NW137] available at https://pmg.org.za/committee-question/12391/.

section 6 wants to maintain rights, but insofar as it lists, and in doing so changes, rights under PAJA, under POPIA and the CPA, but in effect limits and excludes rights.

It is also in this exclusion that section 6, in contravention of section 3(4) of PNHIA, actually does change the functions and powers of the courts, the limitation of the right of access to healthcare only with reference to the criterion of "reasonability"[36] (in conflict with section 36), the various sets of professional legislation that authorise specific professional Boards or Councils to investigate, and act on "professional standards of care",[37] etc.

Simply put, the PNHIA **cannot say "we adhere to right"** in section 6, **but then limit this adherence** through wording in that section. It can also **not say "we don't change powers and functions"** in section 3(4), **but then we do exactly that** by changing powers and functions.

Further examples of the problems created by the amendments (and not upholding of-) other laws and rights in the PNHIA is the amendments to the Compensation for Occupational Injuries and Disease Act, 1993 (COIDA), and the Road Accident Fund Act, 1996 (RAF). These amendments, as contained in the Schedule to the PNHIA severely curtail and therefore "derogate" from the rights currently afforded to beneficiaries under these two systems. Currently RAF and COIDA beneficiaries have entitlements that responds to their specific needs, fees are paid according to the specific nature of the injury, disease or accident, and would conceivably, exceed what would generally be available under the NHI, in particular if the NHI initially would only provide PHC, and some secondary care.

It is unnecessary for the PNHIA to repeat laws that in any event would, and should apply unfettered as per each law's sections on application, to the NHIF and its users. These include, amongst others the PAIA, POPIA, CPA, PEPUDA, the HPA, Pharmacy Act, etc. The professional laws would be the appropriate instead of the provisions in section 6(g), but also section 11(1)(k) and section 39(8)(k).

Within available resources: necessary care, or comprehensive care?

Section 6(1) also states, as does the Constitution "within available resources". This repeat however does not help as a "legislative measure", which, under section 27, would have to give details as to how, and according to which principles, it would limit, and also progressively realise, the rights of access to healthcare. What appears to be a right is only that what is "necessary" and "quality" health care services, free of charge. Neither "necessary" nor "quality" is defined in the PNHIA.

The qualifying "**necessary**" also appears in sections 7(2)(c) as a reason for transfer of a patient and in section 8(2)(b) as an exclusion, i.e. if a patient seeks care that is not "necessary" the NHIF will not cover the care. Mention is however also made to "additional health services" that may be "necessary" under section 32(1)(d), but as a function of the NDOH. "Comprehensive care" now appears to become only "necessary" care. However, neither "**comprehensive care**"[38] nor "necessary care"[39] are set as principles for the work of the Benefits Advisory Committee. In section 10(1)(h) the NHIF "must … ensure … funding … consistent with … **primary, secondary, tertiary and quaternary services**", which again specifies the comprehensive nature of what the NHIF will have to cover. Section 41(5), dealing with the obligations to use the HPRS, also introduces a new concept, not defined, and not found elsewhere in the PNHIA, namely "**rationing of treatment**", which seems to suggest that at stages, not comprehensive, but "rationed" care would be provided. Then, just to add to the uncertainty, section 55(1)(x) envisage **regulations** on "the scope and nature of prescribed health care services and programmes and the manner in, and extent to which, they must be funded", it being unclear what (and where) "prescribed" health care services are being referred to here.

[36] Section 6(d).
[37] Section 6(g).
[38] Section 1, that "strategic purchasing" means that relating to "comprehensive health care services"; section 15(3)(b) that the NHIF Board advise the MOH on the development of a comprehensive package (through the BAC, but the BAC section does not refer to any criteria); and section 39(8)(a) on being kicked off the system for not rendering care that "comprehensive", or being kicked off for rendering than what is not deemed "medically necessary" (section 8(2)(c)).
[39] Sections 6(a); 7(2)(c); 8(2)(c); 32(1)(c) in relation to "additional services"; 36(4)(a) for emergency payment adjustments.

Not only is the above, as to what exactly the NHI would cover, confusing and contradictory, it is also raising hopes amongst the general population that the NHIF would be able to cover all care, comprehensively so, and free of charge. There is no indication of any staging, staggering or criteria for the limitation of entitlements under the NHIF.

HealthMan suggests that, where benefits for a condition is afforded, these benefits must align with what is deemed to be "evidence-based medicine" (as per its current technical definition[40]), as this ensures ***appropriate*** care to users.

To complicate matters further, the PNHIA in section 7 and the long title of the PNHIA refers to contracting to address the "health needs of users". Are "health needs" equivalent to "necessary" care and is that equivalent to what "comprehensive health care services" are?

Waiting times?
Ito section 6(f), a concern is the capacity of the state to make a determination on reasonable and unreasonable **grounds for denial of care**. What benchmarks will be used to determine a reasonable waiting time for services? The OECD average waiting time for cataract surgery is 120 days, but Estonia, with a single payer NHI system has a four-year waiting period for such surgery.

Other concerns in relation to section 6
The communication implications of realising sections 6(b), (c) and (n) are massive – have the realisation of these rights within the NHIF been costed? In any event, it is unclear what the difference between information on benefits (section 6(b)) and information on funding (section 6(n)) is, also given that care would be either free, or not paid at all.

The right of a user to **lodge complaints and appeals** against the Fund, while on the face of it presents a recourse, is actually meaningless if not capable of expeditious implementation. A decision relating to the denial of care could have a severe and irreversible impact on a person's health (e.g. in the case where disease progression can be slowed or halted through treatment), or lead to death, or an earlier death. It is also concerning that there are no jurisdictional boundaries under this section, section 7(6) and the accompanying sections 42 – 47. Complaints can be lodged on fraud, but also on quality of care, which aspects are already under the jurisdiction of criminal authorities and the OHSC, or, where applicable, healthcare professional councils. Given the funding constraints of the NHI, HealthMan proposes that bodies with overlapping jurisdiction not be created.

Role of medical schemes and the limitation of choice
There is an alarming regression from the Draft Bill in respect of the ability of persons to fund their healthcare by means of medical scheme membership/ private medical insurance. The PNHIA will now impose a limitation on the rights of persons to obtain access to healthcare, and access to social security (i.e. social health insurance) elsewhere. This is, globally, nearly unprecedented. In instances where the Fund decides not to provide cover for a particular person's medical services, that person will be unable to access healthcare at all. The Fund will determine whether a person may or may not receive healthcare, and notwithstanding the arduous appeals process, is ultimately dependent on the MOH allowing whatever care is needed, as "complementary" under the PNHIA.

The above is particularly ironic, given that section 6(h) gives **people the right to make "reasonable" decisions** about their healthcare. Within the NHIF, decisions are severely curtailed by referral pathways, formularies and treatment guidelines, as well as whether a facility is accredited or not, whether care is "complementary" or "NHI benefits", etc. All of these are limitations to section 27, and subject to

[40] See, for example, Masic *et al* "Evidence Based Medicine – New Approaches and Challenges" Acta Inform Med. 2008; 16(4): 219–225: "Evidence based medicine (EBM) is the conscientious, explicit, judicious and reasonable use of modern, best evidence in making decisions about the care of individual patients. EBM integrates clinical experience and patient values with the best available research information", available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3789163/.

assessment as to its alignment with section 36 of the Constitution, namely, are such limitations reasonable and justifiable in an **open** and democratic society based on human dignity, equality and **freedom**. The limitation of rights where the exercise thereof does not detract from the rights of others, does not appear justifiable.

3.8. Section 7: Health care services coverage

(1) … the Fund, in consultation with the Minister, must purchase health care services, determined by the Benefits Advisory Committee…
(2) Subject to subsection (4)—
(a) a user must receive the health care services that he or she is entitled to … from … registered …;
(b) … portability of health services as may be prescribed must be available …;
(c) … not be able to provide the necessary health care services … must transfer the user … as may be prescribed;
(d)(i) must first access health care services at a primary health care level …;
(ii) must adhere to the referral pathways prescribed …;
(iii) … is not entitled … if he or she fails to adhere … referral pathways;
(e) … must enter into contracts …. at primary health care and hospital level-based level … based on the health needs of users and … referral pathways
(f) … seamless provision … at the hospital level …
(i) the Minister must, by regulation, designate central hospitals as national government components … with section 7(5) of the Public Service Act ….;
(ii) the administration, management, budgeting and governance of central hospitals … competence of national government
(iii) the management of central hospitals must be semi-autonomous with certain decision-making powers … delegated by the national government;
(iv) central hospitals must establish cost centres

Large parts of clause 7(2) overlaps with section 6, and the slight variations in wording could have massive implications in terms of legislative interpretation, and legislation or its application, being challenged.

Pathways instead of coverage?
Overall, section 7(2) appears to be focused on **referral pathways**, rather than **coverage**. Pathways appear to be the theme in in subsections 2(c), 2(d)(ii), 2(d)(iii) and 2(e). Coverage, in social security law, refers to persons who receive the benefits of the specific social security mechanism, such as the NHIF, and the benefits offered to cover the risk of, in this instance, the realisation of the **risk of ill health**. In simple terms, coverage refers to the extent to which the specific social security mechanism or mechanisms cover the specific risk. It is about beneficiaries and benefits. Section 7 appears to deal with *where* health care is obtained, and in which *sequence*, not with coverage.

Section7(2)(c) could place the onus on the practice to transfer patients that arrive at the facility requiring inappropriate services. Should a male patient[41], for instance, arrive at a gynaecology practice seeking services for a headache, the practice would be required to transfer the patient to an appropriate facility. There is no further expansion on whether ambulance services could be utilised for such transfers, if the practice does not have its own patient transport available, or whether there will be any coverage of costs should the practice remain responsible for the transfer. In the absence of prescribed terms, this clause remains problematic.

The **implications of skipping referral pathways** under section 7(2)(d) is also interesting. Subsection (iii) states that where a referral pathway is not adhered to, the NHIF will not cover the care. This means, when read with the definition of "complementary cover", that medical schemes may cover services not

[41] Business Live interview 13 August 2019, available at: https://www.businesslive.co.za/bd/national/health/2019-08-13-watch-the-dire-warning-for-medical-aid-schemes/.

covered by the NHIF. However, section 33 states that a **medical scheme** may only offer "complementary cover", which appear at odds with the contention that, when for example choosing care outside of the NHI formularies or treatment guidelines, or skipping a referral, which may relate to "core" NHI benefits. Therefore, the contravention of any NHIF rule, such as going to a non-contracted or non-accredited PHC provider, **would, by definition, make the care sought "complementary"** and therefore possible for being offered as funded care by medical schemes. Given the interview by Dr Sipho Kabane, the Registrar and CEO of the CMS, namely that schemes will not be able to offer the same benefits as the NHIF, there seems to be an inconsistency between the wording in the PNHIA, and the stated intention to prevent schemes from offering benefits in parallel to the NHI.

Blurring the line on the purchaser and provider split: reorganizing districts and hospitals

Although an attempt is made to justify the blurring of the purchaser line with that of provider in subsection 2(f)(i) – (iii), by referring to it being necessary for "seamless" service provision, this section in effect creates a re-organisation of the health sector as a provider of services, in contravention of section 3(4) of the PNHIA. Such a re-organisation, in particular where District Health Authorities and public hospitals all would now resort under the NDOH, can only be brought into effect in the NHA, provided that this would in effect be lawful and constitutional.

Section 7(2)(f)(i) compels the MOH to designate central hospitals as "national department components", thereby effectively transferring all staff, assets, etc. from the PDOHs to the NDOH. The same is done in section 32(2)(c) in relation to the District Health Management Offices (DHMO)s, and by implication in subsection (2)(b), also tertiary, secondary and emergency services whoever, in section 32 without the reference to the Public Service Act (PSA).

A careful reading of the relevant provisions of the PSA shows that this may indeed **not** be possible, and the certification of this aspect by the OSLA as constitutional, appear to not have considered this:

- Section 7(5) requires a proclamation by the **President**, to "establish" or "abolish" any national or provincial government component. The PNHIA incorrectly states that the MOH must "designate" by Regulation" central hospitals as "national government components".
- As this would mean an amendment to the current PDOH and the NDOH components, this would have to be done on "**at the request of the Premier**" in terms of section 7(5)(b) and "**at the request of the MOH**" in terms of section 7(5)(a).
- Even if requested by all nine premiers, this is, however, subject to section 7A. Section 7A(1) requires a **feasibility study** has been conducted – there appears to have been none. These feasibility studies would need to be done per province, and on the NDOH.
- Section 7A(3) states: "***No power, duty or function*** *regarding the realisation of a right contemplated in section 26,* ***27****, 28 or 29 of the Constitution and other prescribed powers, duties and functions,* ***may be assigned or delegated, allocated or transferred*** *in terms of subsection (2) (b), (c) or (d)".* This provision seems pretty clear that functions afforded by the Constitution, namely those of provinces to have concurrent powers on the provision of health care services (section 27 and Schedule 3 of the Constitution), cannot be amended by means of the PSA.

Hospitals re-organised by the PNHIA: autonomous, semi-autonomous and/or legal entities?

Section 7(2)(f) is misplaced not only in the text of the PNHIA, but also as relating to the organisation of the provision of health care services. Apart from the above concerns relating to the PSA, section 7 moves administrative arrangements (e.g. administration, management, "minor" infrastructure, human resource management, establishing cost-centres, budgeting, etc.) which should fall within the scope of the executive's powers, into the realm of the legislature. It thereby removes the inherent discretionary nature of such administrative powers. This violates the principle of separation of powers, and all instances where this is being done, i.e. an instruction given as to how administration must take place, must be removed from the PNHIA.

The contracting with these re-organised central hospitals, is problematic. Oddly so, the reorganisation of tertiary and regional hospitals is governed by section 32(2) under the heading of the role of the NDOH and not in section 7, and referred to as "autonomous" legal entities.

In order for the NHIF to contact directly with a central, or an "autonomous" tertiary or district hospital (whose funding will somehow be moved from the PDOHs to the NDOH, these hospitals would have to be juristic persons. In order for a "government component" to act independently, and be added as such to not only schedule 1 of the PSA for employment law purposes, and be designated as "**trading entities**" under the Public Finance Management Act, 1999. Monies received by trading entities are not paid into the general revenue fund, and unless otherwise approved, the DG of Health would be the head of the trading entity. The obligations set out in sections 38, 40, 41 and 45 of the PFMA is significant, and would place additional obligations on the CEOs of central, tertiary and regional hospitals. There are 10 central hospitals, 24 tertiary hospitals and 64 regional hospitals, which would mean the addition of 98 trading entities to the responsibility of the NDOH and the DG of Health. It is unclear whether the 277 district hospitals will therefore remain under the control, and receive budget, from the Provincial Equitable Share (PES). This would be odd, given that it seems that the DHMOs will also become "national government components" (section 32(20(c)).

Alternatively, each of these hospitals would have to become schedule 3 entities under the PFMA, which would make them true independent, legal entities. This would however be extremely complex.

It appears to HealthMan that the implications, and practical implementation of the provisions contained in sections 7(2)(f) and 32(2) have not been properly legally constructed in terms of the PSA and the PFMA, and that the inclusion of policy decisions in legislative frameworks are, constitutionally, problematic. This makes the PNHIA unsuitable to be processed and passed by Parliament, as political decisions cannot be made at this late stage.

(4) Treatment must not be funded if a health care service provider demonstrates that—
(a) no medical necessity exists for the health care service in question;
(b) no cost-effective intervention exists for the health care service as determined by a health technology assessment; or
(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

There are no provisions in the PNHIA for how, when or by whom the "complementary list" (section 7(4)(c)) will be set.

Given the benefits that will be set by the NHI, it would be strange to require individual decision-making to be "monitored" in the way proposed by this subsection. It is unclear how this would work in practical terms, i.e. will there be some form of *ex post facto* oversight or peer review, and if so, who will undertake this? Only persons duly registered, trained and experienced are able to make pronouncements on care provided by others in the same professional category. If the finding is that the treatment is not medically "necessary", who will be held liable – the patient, or the provider / establishment, and, in the case of the "all-inclusive payments" for specialist and hospital services (section 41(3)(b)), where more than one provider might have been involved, how will causality to the "unnecessary" care be determined and made good? As then being "complementary cover" (i.e. not part of the NHI benefits), such treatment could then be funded by the patient's medical scheme, would schemes allowed "late claims", or would the obligation fall on the patient to fund such care out of pocket? Given that patients only have the right to make "reasonable decisions" under section 6(b), it is not inconceivable that a reasonable decision might still be deemed by the NHIF to relate to "unnecessary" care.

(5) If the Fund refuses to fund a health care service, the Fund must—
(a) provide the user concerned with a notice of the refusal;
(b) provide the user with a reasonable opportunity to make representations in respect of such a refusal;
(c) consider the representations made in respect of paragraph (b); and

(d) provide adequate reasons for the decision to refuse the health care service to the user.

Section 7(5) appears to allude to some system of pre-authorisation, where the NHIF would receive requests for funding, and then grant, or deny this. It is difficult to see how such a managed-care type system would work in an NHI, with representations made and reasons being provided in each specific case.

For HealthMan sections 7(4) and (5) illustrates the ambivalence in the NHI system – it seems to not trust a system where care is provided without systems of pre-authorisation and/or *ex post facto* assessment of such care. Where a per event fee is paid, but the providers and establishment is satisfied with that fee, and the patient outcomes are satisfactory, should the NHIF really dig into the aspects of the care rendered, and assess whether the various components of the care was cost-effective, necessary, included in the formulary, etc.? The PNHIA seems to want to implicitly impose a system of managed care on top of the NHI, but without regulations such as those applicable to medical scheme beneficiaries, and designated to ensure the appropriateness of such pre-authorisations and assessments. These activities, as well as the processes of providing reasons, allowing for representations and the likes also have to be costed.

The ambivalence is also clear where the term "reimbursement"[42] is used in the PNHIA, which appears to also refer to some *ex post facto* claim being made, assessed and then (timeously) being "reimbursed" or declined.

3.9. Section. 8: Cost coverage

(1)A user of the Fund is entitled to receive the health care services purchased on his or her behalf by the Fund from an accredited health care service provider or health establishment free at the point of care.

Section 8(1) is again a repeat of sections 6(a) and 7(2)(a).

(2) A person or user .., must pay 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 …;
(b) fails to comply with referral pathways …;
(c) seeks services … not deemed medically necessary by the Benefits Advisory Committee; or
(d) seeks treatment … not included in the Formulary

Once again implies schemes can, or should be able fund services when referral chain is skipped, or out-of-formulary drugs or uncovered services are utilised. As discussed above as part of section 7(4) on when the NHIF will not fund care. However, where such care is indeed available as benefits in the NHI, schemes are prohibited from offering it, then leaving such patients with no access to social security at all. It also indicates that foreigners, who are not allowed to register with the NHI Fund to access services, can join medical schemes to get full funding of all healthcare treatment they require, i.e. more than just "complementary" care. Foreigners therefore have rights that NHI registered users do not.

The issue of exclusions or exceptions from the **formulary** (sections 7(4)(c), 8(4), 38(4) to (6); 39(2)(b)(iii); 39(8)(d); 40(3)(c); and 55(1)(o)) is of specific importance to the members of the HealthMan. It is assumed that formularies (and lists) will apply to both medicines and medical devices, as well as IVD tests. Although non-compliance with the formularies and lists are clearly indicated as extremely important, as non-

[42] See: definition of "complementary cover … not reimbursed by the Fund"; "provider payment … uniform reimbursement strategy"; section 10(1)(e) – timely reimbursement; section 25(5)(b) – reimbursement of services determined by the BAC; section 35(4) and 41(1) on reimbursement "on a capped case-based fee" for emergencies; section 39(5), conditions for reimbursement; section 40(1) that the information platform must include "contracting and reimbursement"; section 41(3) that suppliers and providers must be accredited before they can be reimbursed; section 55 – regulations to stipulate clinical information and codes "for reimbursement" purposes; etc.

adherence thereto will lead to users not receiving free care and providers potentially being kicked off the system, the following concerns arise:

- According to which principles will these formularies and lists be set? The only criteria appear to be that the products must be on the **EML and EEL** (which are, however, not even inclusive of all products currently available on tender in the public sector, and which processes are not underpinned by law or formal engagements with the professions within specific fields of health care). It is proposed that all formularies and lists be set on the principles of **evidence-based medicine**.[43]

- There are **no exceptions to the Formulary or List**, save for a potential undefined and un-provided for "complementary list". The **most vulnerable patients** are those who do not respond on formulary or listed treatments, those who experience adverse reactions, those who suffer harm or would suffer harm as a result of having to use such treatments. In constitutional terms, HealthMan strongly advises that these criteria be included in the PNHIA so as to ensure that vulnerable patients are able to also access appropriate care, without risk of harm, in line with the principle of substantive equality.

- Health technology assessments (section 7(4)) are not technically possible with all medicines (e.g. in rarer diseases), all medical devices (e.g. because of the nature of the device, such as dressings) or all IVD tests. Although HealthMan supports the HMI's recommendation of **economic value assessments**, these could, and should go beyond the mere technical pharmaco-economic assessments and HTAs, for which South Africa in any event do not have the data, or the necessary skills sets in adequate numbers to undertake such a task, and to exclude from the ambit of the NHI benefits products and procedures for which such data and outcomes do not exist. A much simpler, negotiated agreement on a value-offering, including advances in science, research and technology, may be as beneficial to the health system, as a product that has undergone lengthy and expensive formal assessments.
- In spite of the inclusion in section 38(5), the NDOH track-record in updating the EML and the PMBs. (where reviews every two years hardly ever took place, as noted by the HMI as one of the regulatory and leadership failures) is not good.

3.10. Sections 9 – 11: establishment, functions and powers of the NHIF

The National Health Insurance Fund is hereby established as an autonomous public entity, as contained in Schedule 3A to the Public Finance Management Act

Other entities in this schedule to the PFMA. include the Compensation Fund, Lotteries Board, National Health Laboratory Service, the CMS and the Road Accident Fund. As the MOH recently pointed out,[44] such entities find it very difficult to borrow money from markets or banks. This makes the funding shortages a direct government problem, as any funding shortfalls would have to be funded through tax funded government bail-outs, or else service provision could grind to a halt all across the system. There is currently no indication that the NHI Fund would contain a pool of reserves, similar to medical schemes, to assist in periods of excessive health needs (e.g. a cholera outbreak, or a massive natural disaster) and government would have to step in with additional funding, or alternatively service provision might be halted or severely downscaled.

It is also not clear how the trading entities, i.e. the hospitals and DHMOs will function in cases of **funding shortfalls**. This is as there are no longer monies being allocated via the PES, and presumably limited budgets from the NDOH. The main income to cover the costs of rendering healthcare would to come from the budgets or DRG payments from the NHIF. How will a hospital, faced with a catastrophic disaster in a specific area, cope with a sudden influx of patients, or how will the hospital cope with a series of malpractice claims, for example related to a klebsiella outbreak?

[43] See footnote 40 above.
[44] https://www.hasa.co.za/news_stories/nhi-nothing-like-soes-health-minister-dr-zweli-mkhize/

Section 10 (Functions)

… The Fund must -

(a) take reasonably necessary steps to universal health coverage…;
(b) pool the allocated resources … to actively purchase and procure…;
(c) … purchase services … advised by the BAC;
(d) enter into contracts …;
(e) … timely reimbursement … to achieve equity;
(f) … regular, appropriate and timeous payment …;
(g) determine payment rates annually …:
(h) … funding is appropriate and consistent with … primary, secondary, tertiary and quaternary care…;
(i) … implement information management systems …;
(j) … service and performance profile of … providers, … establishments and suppliers;
(k) … paid in accordance with quality and value…;
(l) monitor registration, licensing or accreditation …;
(m) account to the Minister…;
(n) … internal audit and risk …;
(o) undertake research … national health outcomes;
(p) liaise … Department …;
(q) maintain a national database … demographic and profile of the population;
(r) protect rights and interest of users …;
(s) enforce compliance with the Act;
(t) … incidental …;
(u) operate ….Act and all other applicable law at all time

Pooling and benefits

It is not the NHIF that will **pool resources** as per section 10(1)(b), such pooling would take place in the so-called Money Bill envisaged, but not yet seen, and which would financially enable the NHIF. Section 10(1)(c) also contradicts sections 7(1) and 25(5), which state that the BAC will ***determine* the benefits**, in consultation with the Minister. Section 11(1)(i)(vii) also deals with this matter, stating that the benefits must be "designed" by the Fund in consultation with the Minister.

Price determination or price negotiation?

Many provisions in section 10 is repetitive, with small changes in wording, which creates ambiguity that should best be avoided. For example, there are four provisions dealing with payment that must be timeous, three provisions on levels of payment, namely that there would be contracts and/or **determine payment rates** (it being unclear how this will be done, and what the link would be to the BPC and the recommendations of the **HMI in terms of price negotiations**, a concept and model strongly supported by HealthMan) and payment for "quality and value" (also unclear how that is to be determined. In contrast, section 11(2)(e) refers to "negotiate the **lowest** possible price". In section 11(1)(i) the Fund must implement "**best practices**" on the payment of … providers". Section 41 refers to the payment of an "**all inclusive fee**", which indicates that individual price components (e.g. from various specialists, a facility, therapists, etc.) are not to be price determined, raising the issue as to who will be the negotiating part of these fees are negotiated, or, if set or determined unilaterally, who will provide input and how will this be done practically to consider the inputs by all?

The PNHIA is inconsistent in terms of who will actually be the entity or person determining the fees or prices, e.g. the Minister under section 41, or the Fund either determining, or negotiating under section 11? Or will this be done by regulation, under section 55(1)(b), or will "beset practice" follow sometime in the future? It is this **uncertainty** in not only the wording, but the intention behind the PNHIA that **causes practitioners unease**. The question being raised is – what exactly is the plan, in particular for specialists and non-GP healthcare professionals?

What is meant by "**timeous**" payment is not clear. It is not even clear if, how and for whom there would be some kind of claims process. Under medical schemes legislation, providers must, by law, be paid within 30 days, and process exists for querying a claim submitted. The inability of the Compensation Fund

and RAF to settle claims timeously have led to severe hardship in practices relying on payment of claims from these funds, with some **opting out** of doing COIDA or RAF work. This is also a risk to the NHIF, but no steps or mechanisms are included in the PNHIA to give any peace of mind that the same issues will be avoided.

Data, information and research

The provision on a national demographic database overlaps with the envisaged National Public Health Institute, a Bill that was passed by both houses' committees, but lapsed in Parliament before the May elections. The requirement of "compliance with all laws" rings hollow in light of the provisions in section 3 on conflicts or laws, and the selective application of certain laws, such as PAJA, PAIA and POPIA in various sections of the PNHIA.

Again, the PNHIA is inconsistent and health information – is it now the duty of the NDOH under the NHA, or does it reside under the NHIF? In terms of the duty to regulate the whole health system, and not only the NHI, the NDOH should establish the information system, and the NHIF should not create a parallel system or systems.

(2) … most cost-effective and efficient … in accordance … section 195 of the Constitution and the PFMA…
(3) … must perform … in accordance with health policies approved by the Minister
(4) … must support the Minister …

The Fund will in effect not be independent, as it would, in terms of section 10(3) statutorily adhere to health policies approved by the MOH. The statements relating to the Constitution and PFMA are superfluous, the NHIF would in any event have to abide by those.

Section 11: Powers

(1)…
(g) improve access … purchasing and procurement of … services … goods … of reasonable quality
(h) investigate complaints against the Fund, … providers … establishments or suppliers ..
(i)… best practices … purchasing … payment… delivery … data … risks … fraud
(j) … sponsor health research …;
(k) … prevent corruption, fraud, unethical or unprofessional conduct … abuse of users…;
(l) obtain information from … any other public entity or organ of state;
(m) conclude an agreement … health care services …
(2) … contract … services … products … and must –
(a) … sufficient quantity and quality …;
(b) … no interruption to supply …;
…
(e) negotiate lowest possible price …

The use of the phrase "**reasonably quality**" (section 11(1)(g)) is concerning. It seems to denote that quality (as is actually stipulated elsewhere in the PNHIA), is not needed, only some level of "reasonable" quality. In terms of goods, quality is determined by SAHPRA, for services quality would be assessed by, amongst others, the OHSC, and professional councils. Therefore section 11(1)(h) is also problematic – the NHIF is not a body that should or could **investigate** complaints on healthcare providers or products, the bodies competent to do so is the OHSC and the ombud, SAHPRA, the HPCSA, SANC, etc. To create parallel systems with **potentially different outcomes**, is hugely problematic, and, given the wording of section 3(3) would mean that an outcome of an investigation under the NHIF, where it is different to that of the HPCSA, would effectively override the HPCSA!

Section 11(1)(l) authorises the NHIF to obtain any **information from any public entity**. This goes against the principles set out in the POPIA, and the limitation that would be authorised by the Constitution on justifiable limitations to privacy rights. As stated above, it is unclear what the legal basis is on which the NDOH is currently compiling the HPRS.

Ito section 11(1)(m) and 11(2), and given what as outlined above on the autonomous and semi-autonomous hospitals, the **NHIF would not be able to contract** with hospitals and DHMOs unless the processes under the PFMA on trading entities and the PSA processes (if indeed possible) have been concluded. This is a provision that should actually be in the transitional arrangements of section 57, namely how to contract and change contracting from the province and the NHIF as the contracting parties to the hospitals and DHMOs as the parties contracting with the NHIF.

If public healthcare facilities do not radically improve the quality of their services prior to the implementation of NHI, the NHIF will not have sufficient supply of quality or quantity of services to fulfil its mandate. It is therefore an imperative that public healthcare facilities in sufficient numbers meet the contracting and accreditations criteria prior to implementation. The **quality improvement plans** that follow on OHSC inspections should therefore be a matter of political and budgetary priority.

It is interesting that it indicates the fund will "**negotiate prices**", but only at the "**lowest**" possible level, as pointed out above. But then there will be a Health Care Benefits Pricing Committee which advises the fund on pricing of services. There are references to a "national pricing regimen" (section 39(2)(b)(iv)) in to be adhered to by accredited providers, which indicates price setting / determination as well.

3.11. Sections 12 – 19: Board of the NHIF, CEO and powers of the MOH (sections 31, as well as 7, 10, 15, 33, 38, 39, 41, 42, 51, etc.); role of the NDOH (section 32)

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 these same governance structures in place. The MOH appoints the Board, Board Chair, CEO (section 19 - normally a Board would appoint the CEO), Benefits Advisory Committee and its chair, Pricing Committee and its Chair, Stakeholder Committee and its chair and has the power to remove any of these Committees and appointees. The NHIF, and its Board accounts to the MOH (sections 12 and 15(1)).

Other **good governance principles**, such as the difference between governance and operationalisation, and political oversight and technical decisions, that are **violated by the PNHIA** include:

(a) The Board advises the Minister, and not the Fund or its CEO, on its administration (section 15(3));
(b) Where the Board advises the CEO, it must inform the MOH of such advice (section15(4)(d));
(c) Board procedures, which Boards should be free to set themselves, must be set "in consultation with the Minister" (clause 17);
(d) The CEO is subject to the "directives and determinations of the Board in consultation with the Minister (section 19(4)(b)).

Not only does the MOH make appointments, s/he would also be in the thick of the governance structure, and also have a determining role in the administration and implementation of the Fund. This is truly extraordinary, and effectively gives the MOH a veto over many of the key matters needing to be implemented by the NHIF to fulfil its mandate. This is exactly the type if powers that were at stake in the much-publicised Social Security Agency matter, which landed in the Constitutional Court.[45]

Examples of the **MOH's extraordinary determining role in administrative and technical matters** include have a say in the setting benefits (section 11(1)(i)(vii)); setting referral networks (section 11(1)(i) (viii)); determine the information needed to measure health outcomes (section 39(5)(h); determine the "nature of provide payment mechanisms" (section 41(1)); setting the formulary (section 38(4)) and the complementary list (section 7(4)(c)); in setting up the Office of Health Products Procurement (OHPP – section 38(1)); specify the range of the "minimum range" of "personal health care services" (section 39(2)(b)(i)); determine the NHIF's complaints procedures (section 42(1)); determine that monies paid to the Fund in error, cannot be refunded (section 48(d)); delineate the work of the NHIF (section 31(2)) – this

[45] South African Social Security Agency and Another v Minister of Social Development and Others (CCT48/17) [2018] ZACC 26; 2018 (10) BCLR 1291 (CC) (30 August 2018)

should normally be done by the PNHIA itself; determine when the NHI is "fully implemented" and then prohibit medical schemes[46] to fund care "reimbursable" by the Fund (section 33); and determine what must be in the Annual Report of the NHIF (section 51(2)).

There is too little oversight of the power provided to the MOH not only in governance terms, but also in technical and implementation terms. There is a serious risk of political interference (a non-compliant CEO could face removal, a non-compliant BAC or OHPP could face constant vetoes by the MOH, which could incapacitate the operations of the Fund, at least by inducing delays to obtain the "consult" of the MOH, at most provide opportunities for the introduction of patronage throughout the governance and implementation of the NHI.

A further extraordinary power of the Minister is to, under section 55(3)(b) **publish and finalise regulations** without public consultation, if deemed by him/her "in the public interest" to do so. This is another example of the certification of the PNHIA as constitutional by the OSLA as not properly done. This, together with the extraordinary legal status being afforded to "**directives**" (sections 10(1)(f), 19(4), 54 and 56) provided to the NHIF, violates the separation of powers, democracy and transparency. It amounts to the **unfettered law-making** by the executive.

Only "private" use of information by Board members for profit is prohibited (section 16(2)(c)). Given the structure of hospitals and DHMOs, the use of information gained at the NHIF Board could also benefit public interests, where facilities may be competing for budgets, accreditation and/or contracts. This will be particularly pronounced where DHMOs contract through CUPs.

Sections 31 and 32

The role of the Minister as set out in **section 31** is also superfluous, this is, and should be set in the Constitution and other applicable legislation, and re-stating it in the PNHIA is not necessary, and introduces unnecessary uncertainty as to why certain laws are mentioned, and others not, The PNHIA should only relate to its mandate and the role of the Minister in it, and not elsewhere.

It is equally problematic that section 32 must re-state, and potential thereby contradict the role of the NDOH as set in other legislation. What is problematic is that section 32(2) basically instructs the MOH to exercise his/her executive powers in a particular way, and insofar as it is expression a discretion, this is unnecessary. If the legislature wants changes to the NHA, it should propose so, or request the NDOH or MOH to propose such changes, not suggest so in a different law.

The bulk of sections 31 and 32 should be scrapped as violating the separation of powers.

3.12. Sections 19 – 22: CEO and staff

Given that the CEO would have the mandate to operationalise the NHIF, and therefore the ensure that its powers and functions are executed, the duties listed in section 19(2) and (3) are superfluous.

A further extraordinary provision on the **appointment of senior staff**, which should be the prerogative in corporate governance of the CEO, is being done only with the "written approval" of the Board (section 22). As Board decisions are subject to communication to the MOH, it means that s/he would be informed, and could potentially influence, through the Board, such appointments. This is exactly this operational interference, in particular at CFO and other procurement positions that were evident at the instances of state capture.

3.13. Sections 25 – 30: Advisory Committees (BAC, BPC, Stakeholder Committee)

[46] Here, unlike elsewhere in the Bill, the correct terminology, namely "medical scheme" and not "medical insurance scheme" (sections 6(o), 8(2)) is used.

Three sets of advisory Committees are set by the PNHIA, all having the same gap, namely no real and clear mandate and criteria within which to exercise those mandates, leaving their work to be largely discretionary, and outside of the principle of rule of law.

All of these Committees, although instrumental in the operationalisation of the NHIF, are appointed by the MOH, and must even include a ministerial representative. There appears to be no direct or dotted structural line from these Committees into the NHIF, although reference is made to their recommendations in other sections in the PNHIA. How these determinations and recommendations would reach the NHIF, is unclear.

BAC

In spite of being "advisory", the BAC *determines* and reviews (i.e. they set –

- Health care service benefits (section 25(5)(a));
- Types of services to be reimbursed at each level of care (section 25(5)(a));
- "Detailed" and "cost-effective" treatment guidelines (section 25(5)(b));
- In consultation with the MOH and the Board, the "health service benefits" (section 25(5)(c)).

It is unclear how subsections (5)(a) and (c) differs. It is also strange that a technical function, such as setting benefits, is to be undertaken not be expert advisors and staff in the NHIF, but by the MOH (the political head) and the Board (that should be setting direction on governance).

Most concerning to HealthMan is the fact that healthcare professionals in each "type" and "level" of care are not included in setting (a) treatment guidelines (which should be a professional and scientific activity that can, under professional legislation, only be executed by registered, experienced and skilled professionals in that field) and in commenting on (b) benefits set, so as to provide input on the implications of such benefits, which should be based on, but not necessarily be the same, as treatment guidelines. It is only at benefit-setting level where decisions on cost-effectiveness would have to be made.

HealthMan proposes that Treatment Guidelines be set, according to the recommend dations of the HMI, with professional involvement in each area covered by such Guidelines. Then, if the **BAC uses** the **Treatment Guidelines and the outcomes of value-assessments** (HTA, etc.) **as proposed by the HMI**, it would do so linked to any other funder, to inform the benefits it affords to users of the NHIF. In order to do so, the BAC must, by law, co-opt professionals who are clinical experts, and who could advise on the impact on access to healthcare on the inclusion and exclusion of certain benefits, or decisions made on one treatment modality versus another, when setting benefits.

It would be conflicting for the benefits committee to also be the "scientific" and "health economics" committee.

BPC

Interestingly, the BPC sets the pricing of "service benefits". It is unclear what this means for healthcare providers, establishments and suppliers. If **a benefit** is, for example, all vaccinations contained on the Extended Programme of Immunisation (EPI), would that benefit be priced as inclusive of vaccine costs (including transport and storage), professional fees, facility fees, etc., or does it refer to the fees that a contracted-in provider (e.g. a nursing professional in a pharmacy) would receive for offering that benefit? Or would the BPC *cost* **all benefits** in order to determine the **cost** of such NHI benefits, or would it determine **price** or prices? The scant description of what the BPC would actually do, and recommend on, renders the section vague and unimplementable, and recommendations made subject to legal challenge.

Stakeholder Advisory Committee

There is no mandate for this Committee, and, as with the others, no link to the NHIF or its operations. The composition also excludes suppliers

3.14. Section 33: Role of medical schemes

The matter of medical schemes and the contradictory messages, e.g. medical schemes cannot fund NHI benefits (sections 33 and 6(o)), but may *have* to be able to do so, if a user skips referral pathways or deviates from formularies or treatment guidelines, is perhaps one of the most concerning provisions in the PNHIA (section 8(2)).

Social security rights, as afforded under the Constitution, currently includes medical scheme coverage for incidents of catastrophic and hospital-based care that persons would not be able to afford to cover themselves, out of pocket. Any limitation thereto, as proposed by the PNHIA would need to pass constitutional muster, not only in the limitation itself, but also as to whether the PNHIA is progressively giving effect to the health- and social security rights afforded by section 27. To the best of our knowledge, no open and democratic society prohibits individuals from obtaining, and businesses from offering, cover that may overlap or duplicate with its health social security funds and mechanisms.

It is, in the view of HealthMan unlikely that the exclusion of medical schemes from providing cover for benefits also covered in the NHI, would withstand constitutional scrutiny.

3.15. Section 34: NHIS and Section 40: Information Platform

Section 74 of the National Health Act states that the NDOH must facilitate the creation of a comprehensive national health information system. The PNHIA seeks to transfer that legislative responsibility from the NDOH to the NHI Fund.

To date, this system has not been established by law, as is required and the Minister is yet to publish regulations in terms of section 74(2) of the NHA which would prescribe the details of the data to be compiled collated and submitted to the National Department of Health. Regulations must also determine rules around health records, such regulations are equally not being promulgated.

It seems the PNHIA is seen as a "second change" for the NDOH and MOH to address the regulatory and stewardship failures pointed to by the HMI. However, the wrong legal vehicles are being used to do this.

3.16. Sections 36 and 37: District Health Management Office (DHMO) and Contracting Units for Primary Health Care (CUPs)

Although the clients of HealthMan will not be affected, mostly, by the DHMOs and the CUP, many of the concerns reiterated above, apply here as well. It seems that the PNHIA is used as a vehicle to transform the supply / provider side of healthcare. This should not be done as part of the funding / purchaser part of the NHI, and must be done in the NHA.

The creation of the DHMOs is also significant, as pointed out above, both from removing existing rights, responsibilities and funding from the provinces over districts, but in requiring direct contracting with the NHIF, requiring these to become "national government components".

However, matters get more complex with the introduction of the CUPs. Primary care service providers (and presumably also suppliers) would have to work through CUPs to access NHI users. These **CUP**s are described, under the amendments to the NHA proposed in the schedule to PNHIA, as **contracting directly** with the NHIF. This means that the CUPs would have to become trading entities under the PFMA system. Although the CUPs must, under the new section 31B of the NHA ensure adequate capacity, it is unclear how it should do this, and also how the DHMO would step in (meaning they would then also have to become trading entities) if the CUP is unable to do this, according to section 31B(6).

It is unclear from the PNHIA and the NHA as to what powers the CUPs would have to sub-contract providers as individuals, practices and/or as groups of providers, or whether the public and private facilitate would themselves form a CUP – section 37(2) says the CUP "comprises" district hospitals, clinics

and the likes, as well as private provider networks. The legal status of the CUPs, or its composite units, are not clear. Its ability to contract and receive funds from the NHIF is therefore also not clear.

3.17. Section 35: Purchasing of health services

35 (1) The Fund must actively and strategically purchase … in accordance with need.
(2) … transfer funds directly to … central, provincial, regional, specialised and district hospitals based on a global budget or Diagnosis Related Groups.
(3) … primary health care services must be transferred to Contracting Units for Primary Health Care
(4) (a) Emergency medical services… reimbursed on a capped case-based fee basis with adjustments … severity, where necessary.
(b) Public ambulance services must be reimbursed through the provincial equitable allocation

Section 35(1) refers to need, instead of stating that services giving effect to the NHI benefits would need to be purchased. The use of the phrase "in accordance with need" gives rise to concern. It could also lead to endless litigation against the Fund, as it would have to provide according to need, and not according to the benefits it covers. If a user needs surgery, but the NHIF only initially provides PHC, such a person could rely on section 35 to access any care they **"need"**.

Section 35(2) is significant in that it makes **no provision** whatsoever for the **purchasing of services from private hospitals**, other units, such as physical or substance abuse facilities, mental health facilities **and specialists in private practice**, or **other healthcare professionals not working in PHC** (e.g. psychologists, occupational therapists, physiotherapists, etc.). This is in contrast to section 41 that allows for these entities to be paid an "all-inclusive fee". So, they cannot be purchased from, but they can be paid?

The second problem with section 35(2) is that it lists **district hospitals**, which should be according to section 37, be included in primary care provision, as part of the CUPs. It must also be noted that the specialized hospitals are not included in the sections dealing with the "autonomous" and "semi-autonomous" nature of public sector hospitals.

Section 35(2) is simply about **allocating budgets ("transferring funds")** to these hospitals and does not seem to necessitate contracting or the existence of "trading entities" or "national government components" to access such funds. It does seem that the convoluted system of creating a **plethora of trading entities, moving staff under the PSA, etc**. to solve a basic **accountability problem** at PDOHs is not a rational or reasonable response, and would create numerous obstacles and costs, that would detract from the mandate to provide access to healthcare services, and social insurance to afford such services.

3.18. Section 39: Accreditation of providers

The issue of accreditation, as an example of the conflicting provisions in the PNHIA with other laws, and as an example of the PNHIA blurring the line between being a purchaser, and being regulator, organizing and regulating the provider / supplier side of healthcare, is discussed comprehensively above under paragraph 2.2 and 2.3, as well as elsewhere in this submission where issues of formularies, pricing etc. are discussed.

In addition to what was stated above on section 39, the existing HPCSA rules, although up for amendment, and the provisions of the HPA must be considered. The section 54A proclamation under the HPA prohibits single incorporated entities to be formed that span non-healthcare professionals, or even professionals in other categories, or at other statutory councils.

Also, in this section 39(2), as in section 35(1), the matter of "need" (as opposed to the provision of care in line with NHI benefits) are stated as a requirement. Showing compliance with a system to which one is not contracted, in order to *obtain* accreditation and thus being able to contract, as per sections 39(2)(b)(iii), (iv), (v) and (vi). One may not even have access to the NHI formularies, treatment guidelines, pricing "regimen" (sic.)!

The conclusion of "legally binding" (sic.) contracts with all health establishments is envisaged, however these would have to exclude those that form part of CUPs, it is assumed. This also means that all public hospitals would have to be legal entities, and not just trading entities operating under the NDOH.

Contracted providers and establishments would be compelled to use the HPRS, however there is no legal framework that, in line with the POPIA, governs its access, use, further processing, consents and disclosure to patients as to why the information is collected and how it will be used, no protection on confidentiality, also against hacking and unauthorized access, etc. Any person or entity that supplies, uses and/or processes information on the system without such legal framework being in place, would be in contravention of the POPIA and the constitutional right of privacy.

The requirement to contract only with "accredited" providers and establishments are repeated ad nauseam in the PNHIA, it is suggested that once it is set as a criterion in one section, it is not necessary, and it makes the PNHIA unnecessarily long and verbose, to keep on adding "accredited" or "properly accredited" (section 41(3)) to those nouns.

3.19. Section 41: Payment of providers

After 10 years of Consultation on the various NHI Policy Papers, it is extremely disappointing that there is so little contained in the Bill on how providers will be paid.

The payment of providers is obviously of grave concern to the clients of HealthMan. Statements made in the media that specialists would just have to take some pain, and/or that work should just be re-organised in order to free up spare capacity (e.g. by using task-shifting, or multidisciplinary practices), or that there will be a volume-increase in make up for fee decreases, miss three important realities:

(a) Health care professionals are in existing business configurations, and the re-organisation thereof, including the involvement of other professionals and disciplines, will take time and legislative changes;
(b) Where there are financial and income impacts, and in particular where such impacts are unknown as the payment levels and modalities are as yet unknown, practitioners will make decisions that protect their practices, their staff, and their families;
(c) Not all types of care are capable of scaling in terms of volume, simply due to disease prevalence, or location.

The NHIF will, according to section 41(1), *determine*, in consultation with the MOH the "nature" and "mechanisms" of provider payment. Section 55(1)(b) however states that regulations must be made in this regard. Unlike the regulations empowered by section 90(1) of the NHA, there are no criteria set in terms of which such payment mechanisms, and fee levels are to be set, or, perhaps negotiated.

There are no definitions or explanation of what is meant by "nature" or "mechanisms". However, also the CEO has a mandate under section 20(3)(c) to set up a unit on provider payments, and the NHIF has the power to develop and implement "best practice" in relation to the payment of providers. In addition, section 11(4) allows the Fund to negotiate the "lowest possible price" for services. On top of this, the BPC would set the pricing levels of benefits, which would affect the payment of providers for services which they render, or play a part on rendering as part of the NHI benefits.

In the final analysis, apart from the costs associated with reorganizing a practice, implementing the necessary software and hardware to link into the NHIF and HPRS, there is **no indication as to where the political thinking is on provider remuneration**. Because there is no indication on the political thinking, there are no principles included in the PNHIA. Although many politicians have indicated that they support the implementation of the **HMI recommendations**, the timelines set by the PNHIA, and those set by the HMI, would make such implementation of the HMI recommendations virtually futile, as it requires setting up a statutory body and its systems, and then commencing the system of fee negotiations. The HMI process would take at least five years (i.e. from 2020 till at least 2025), whilst full NHI implementation is

envisaged for 2026. To set up a system that would only be operational for a year, and then become virtually redundant, would be irrational and illogical.

In terms of "all-inclusive" fees, per event fees or capitation, the HPCSA rules currently do not allow for providers to receive funds for services not rendered; which is what happens in Capitation models. This is to avoid the perverse incentives contained in this payment mechanism. With the PNHIA superseding all other regulations, patients will not be able to complain to the HPCSA if a doctor underservices them in such a Capitation Model, as the NHI Act places the Capitation model in place and Supersedes the HPA.

All Inclusive fees in a hospital environment implies an employment relationship between the Hospital and the Specialist, as well as employment of all involved allied healthcare professionals, and indications are that the HPCSA are not keen on this model. One of the major absences is any indication of payment for specialist services outside of the hospital environment. Mental healthcare patients need to be followed up by psychiatrists outside hospital and treatment of eye conditions which require intravitreal injection also needs to happen in a specialist space, outside of the hospital environment. There is no reimbursement mechanism mentioned for such services. Research[47] shows performance based payments are limited to in-hospital services and primary care initiatives at present.

3.20. Section 38: The Office of Health Products Procurement (OHPP)

One of the practical oddities of the PNHIA is that it creates the OHPP, but that entity would not, and could not procure or financially transact or pay any supplier of goods on behalf of the NHIF. Section 38(3(c)) states that the OHPP will "coordinate … supply chain management and price negotiations", but "accredited provider(s) and health establishments must procure" according to the Formulary. This means that no supplier will sell to the NHIF, and all suppliers will sell to public and private hospitals, private providers, etc. It also has a practical administrative impact, instead of having nine (or perhaps a few more) public sector accounts, suppliers would now have to create accounts for every public sector trading entity (hospital and CUP) they sell to. For the private sector, wholesalers would be excluded, as suppliers are under section 38(6) obligated to supply directly to the provider or establishment, and not via a third party.

For private practitioners and private hospitals this raises an interesting conundrum – existing suppliers would have to be switched to the NHI-set suppliers of products on the NHI formulary. This would also go for equipment and would necessitate changes in brands of products, in particular medical devices in order to fit with consumables, disposables and even medicines on the NHI Formulary. This also raises a legal liability question – if Formulary products are out of stock or cause harm to a patient – who carries this **legal liability**?

HealthMan proposes that, where providers are paid an all-inclusive fee, the choices of products, the procurement and price negotiations (including potential risk-sharing) should be left to the providers. This, however, assumes a free pricing regime where the NHI or the public sector are not the procurers.

Section 38(7) creates yet another internal inconsistency in the PNHIA: it states that the PFMA and PPFA must be followed during **tenders**. During tenders, companies put in bids, according to a system of free pricing. However, section 11(4) states that the NHIF will negotiate the lowest possible price with suppliers. The Schedule to the PNHIA, amending section 22G of the Medicines Act, says that medicines can only be sold (a) to the NHIF, and (b) can only be sold at the Single Exit Price (SEP) to the whole market. Furthermore, the benefits pricing levels recommended by the BPC and the inclusion or not of a medicine on the EML, or a device on the EEL, would affect product availability, and therefore patient access.

[47] Cheryl Cashin, Y-Ling Chi, Peter Smith, Michael Borowitz and Sarah Thomson, 2014. *Paying for Performance in Health Care- Implications for health system performance and accountability.* The European Observatory on Health Systems and Policies

So, the question therefore is, will prices be pre-determined or set (e.g. as a new, presumably lower SEP), will it be based on bids, will it be based on negotiation, or will it be based on some other consideration? Again there are no indications, political other otherwise, as to the direction that will be taken, and the potentials product **pricing regimes created in the PNHIA are mutually exclusive** (price setting, price negotiations and bids).

3.21. Sections 42 – 47: Complaints and Tribunal

The issue of overlapping and contradictory jurisdictions on matters that could give rise to patient complaints and disputes, or complaints and disputes between the NHIF and providers, establishments or suppliers, have been addressed above. These sections have the potential to generate massive expenditure for NHIF, and its necessity should be seriously re-considered. A complaint- and referral system would be less complex and costly. The OHSC, SAHPRA, SAPC, SANC, HPCSA, AHPCSA, NRCS, NDOH, CMS, etc. as well as the High Courts or special courts for matters relating to consumers, POPIA, PAIA and PAJA are adequate to deal with all matters that could arise during the NHI and its implementation.

3.22. Sections 48– 49: Funding

There are two distinct funding issues in the NHI, one being the funding of the NHIF and its structures, the second the funding of healthcare. The finding of the NHIF and its structures can be set in the PNHIA, however, the funding of healthcare and kin particular the re-allocation of the PES, payroll- and other taxes, etc., must be set in a so-called Money Bill. All references in the PNHIA to aspects of the funding of the NHI benefits must therefore be removed.

Section 49 in particular is again **internally inconsistent with section 3(4),** namely that the PNHIA does not change any funding or functions of any organ of state.

3.23. Section 53: Confidential information

This section is superfluous in light of the references elsewhere in the PNHIA and the other pieces of constitutional legislation, such as POPIA and PAIA. It is however also internally contradictory as obligations to share personal information of patients into the HPRS, outside of the provisions of POPIA, are contained in section 39.

If the POPIA applies, it applies to its full extent, and the whole PNHIA should ensure that it provides for the mechanisms required by POPIA to be compliant, e.g. stipulate the purpose and uses of the information processing; requiring consent to processing and any future or further processing; etc.

3.24. Section 54: Offences and penalties

The most concerning aspect about section 54, is failure to follow a Directive of the NHIF or its Board, could amount to an offence in terms of clause 54(2) of the Bill, attracting a fine or even imprisonment. This means that a non-legislative tool could lead to criminal sanction. This violates the principle of the rule of law, and substitutes it with the rule of a political appointee, or an organ of state, outside of the rule being one of law.

3.25. Section 55: Regulations

55(1) … the Minister may, after consultation with the Fund and the National Health Council… regarding –
(a) the legal relationship between the Fund and the various categories of health establishments, health care service providers or suppliers …;
(b) payment mechanisms …;
(c) the budget of the Fund …;
(d) … the national health information system…;

(e) clinical information and …. Codes …;
(f) … national health information system … and the HPRS …;
(g) the registration of users …;
(h) the accreditation of providers, establishment and suppliers;
(i) the functions and powers of the District Health Management Office;
(j) the functions and powers of the Contracting Unit for Primary Health Care Services;
(k) the relationship between the Fund and the Office of Health Standards Compliance;
(l) … relationship … Correctional Services…;
(m) the relationship between public and private health establishments … ;
(n) … relationship … Medical Schemes …;
(o) development and maintenance of the Formulary…;
(p) investigations …;
(q) appeals…;
(r)… providers, … establishment and suppliers … reports …;
(s) … monitoring and evaluation…;
(t) … fees…;
(u) … reserves …;
(v) … money … invested …;
(w) … practices and procedures to be followed by providers, … establishment and suppliers…;
(x) the scope and nature of prescribed health care services and programmes and the manner in, and extent to which, they must be funded;
(y) proceedings of the meetings of committees;
(z) … proceedings … Tribunal;
… any other matter…

It is noteworthy that the regulations are to be made **after consulting with the NHIF and the National Health Council**, a body created under the NHA with no mandate in the NHIF. As the National Health Council is about the organization of the health system as a supplier and also as a regulator (e.g. in terms of research, human tissue, and quality standards, inspections, etc.), their role should be limited to the NHA and not be expanded by the PNHIA into the NHI as a purchaser/funder.

Various sets of regulations are envisaged, some of which overlaps with legislative mandates for such regulations set elsewhere:

- Subsections (d), (f), (i), (j) and (m) are regulations that must be set under the NHA, as it pertains to matters already in the NHA or as part of the organisation of the health sector which falls within the mandate of the NHA.
- No regulations are in place for the Essential Medicines- or Essential Equipment List as per the NHA, and the Formulary, which is to be built on these, and its accompanying regulations would therefore be incomplete.

It is unclear what section 55(1)(a) envisages in terms of the "legal relationship" between the fund and suppliers, providers and establishments. The PNHIA makes it clear that these would be contractual relationships, and also a relationship where these entities will be accredited (section 55(1)(h) – it however being unclear what exact accreditation of suppliers will be undertaken, given the controls of SAHPRA, SANAS and NRSC over products).

Ito section 55(1)(u), as with the Money Bill The reserve levels of the fund, being a good example. A more comprehensive set of accompanying Regulations should have been published alongside
the Act, so that the public could engage with the legislation in totality.

3.26. Section 57: Transitional arrangements

Section 57 does not contain transitional arrangements, as there are no existing NHI-type arrangement or structures that, through the PNHIA must transition into something else. The bulk of the issues listed in the

section relates to policy and pre-implementation steps. These relate to the activities of the executive, and not the legislative authority.

What should be transitional provisions, but are not, are the arrangements for the transfer of staff from the provinces, and the arrangements of the transfer of hospitals and DHMOs from PDOHs, to the NDOH. Arrangements in relation to existing contracts, e.g. with suppliers, providers (including PPPs), as well as legal obligations (debts, medico-legal claims), etc. are however absent. The status of decisions, policies and laws made by PDOHs are also left hanging. So is the necessary changes to the PES, and the role of the Financial and Fiscal Commission, set up in terms of the Constitution to look at equitable share and other allocations of state resources.

The *laissez faire* manner in which the Bill was reviewed and presented to Parliament is clear from this section – dates were not updated (section 57(2)(a)), activities now no longer in the PNHIA (such as the HTA body or the Governing Body on Training, etc., all "set up" by section 57(3)) or amendments to the NHA or elsewhere are still included in this section, etc. It also raises issues (pathology services through the NHLS – section 57(4)(g)(iii). and refers to healthcare professionals ("audiologists, oral health practitioners, optometrists, speech therapists and other designated providers" in section 57(4)(f)) not referred to the PNHIA itself, leaving one at a loss as to whether these professionals would fit.

Section 57(h) also instructs amendments to other laws, which is the prerogative to be introduced by the NDOH or MPs. However, some of those changes are already included in the Schedule to the PNHIA and apart from some of these laws not falling with the ambit of the NDOH or PDOHs, are nonetheless proposed to the changed in specific ways.

Sections 57 (4)(g)(i) and (5) again usurps the powers of what would have to be contained in a Money Bill, and should be removed from this section.

4. Drafting errors

The PNHIA, in its Bill format, as before Parliament, is unfortunately riddled with drafting errors, some of which, such as those relating to definitions not being provided, inconsistently used, etc., as discussed above. Others include:

Laws are sometimes referred to by their full the "Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)", but sometimes merely as the "National Health Act".

The use of dates that have already passed in section 57.

The incorrect inclusion of policy matters, and matters reserved for the executive branch throughout the PNHIA, and a kind of summary of the NHI White Paper in section 57, which also, oddly so ENVISAGES the very law before Parliament as having to be drafted still, as well as dictating some future revisions of laws, whilst not actually engaging and ensuring that such amendments are being effected to ensure an implementable law.

5. Conclusion

The NHI Bill in its current format is legally flawed and un-implementable. There are a number of Constitutional concerns which have not been appropriately considered by the State Legal Advisor and are bound to be challenged in court, once the Bill is enacted. The concerns of ***HOW*** the provisions of the Bill will be practically implemented remains opaque and a large number of the contained proposals could take decades to implement. Other shortfalls, such as capacity constraints in the Office of Health Standards Compliance, are simply ignored. HealthMan urges government to withdraw the Bill and republish it once the associated Money Bill and all accompanying Regulations and structural framework is in place, for informed consideration as a whole. One cannot comment appropriately on such an incomplete framework.