SASCI
South African Society of Cardiovascular Intervention

SUBMISSION ON BEHALF OF SASCI Private Practice Committee

ON THE NATIONAL HEALTH INSURANCE, 2018

21 SEPTEMBER 2018

1. About SASCI

South African Society of Cardiovascular Intervention (SASCI) is an organisation of physicians; scientists and allied professionals with the purpose to advance the development of cardiology and coronary revascularisation and to provide minimally invasive; image guided diagnosis and treatment of cardiac medical conditions. It also acts in an advisory capacity to funders; industry; members and the government on matters relating to interventional cardiology. The latter is a branch of cardiology that deals specifically with catheter-based treatment of heart diseases and includes procedures such as angioplasty and Trans Aortic Valve Implantation (TAVI). SASCI feels that our submission is important to act in the best interest of our patients.

SASCI is affiliated as a Special Interest Group with the SA Heart Association and developed this submission with support from another SA Heart Special Interest Group CASSA (Cardiac Arrythmia Society of Southern Africa).

This submission has been prepared by the Private Practice Committee (PPC) of SASCI with input from private practice cardiologists from CASSA. For this submission SASCI must been viewed to mean SASCI PPC.

2. Introduction

SASCI does not address all clauses in the Bill, and focuses on the matters most pertinent to interventional cardiology. SASCI is more than willing to engage further on any matter it raises in its submission.

SASCI believes that many pre-conditions for the NHI are not yet in place, some of which have been pointed out by the HMI, some of which is evident from the human resource difficulties in the public sector, the public sector quality reports of the OHSC, and, most importantly. The lack of clarity on how the NHI will be funded.

The passing of a law in the absence of an enabling framework to ensure its successful implementation could, in SASCI's view, cause considerable harm to the health sector at large. Statements such as those made in the media, that the private sector should be made "less lucrative"[1] is not helpful, neither is that hopes that are raised

[1] https://www.news24.com/SouthAfrica/News/our-doctors-walk-away-20180909-2.

amongst the general population that there would be more, and better access, to healthcare, also through the use of phrases such as "comprehensive care" at "no cost".[2]

In SASCI's view, should the various provisions of the National Health Act, to date unimplemented, or not completely implemented, be implemented, progress will already have been made in achieving universal coverage. Instead, it seems that the NHI is duplicating provisions on the relationship between the public and private sectors, the services that should be rendered at various health facilities, the referral system, etc.[3]

A hasty parliamentary process and implementation before the elections next year, without ensuring the right conditions being in place, would also not align with the Constitution of the Republic of South Africa. The Constitution requires that the right of access to healthcare to be implemented, namely within its available resources, in a progressive fashion. The Bill is not drafted as a piece of legislation that speaks to progressive implementation, or that considers whether, as in terms of section 27(1)(c) of the Constitution, persons are able to provide for their health through social insurance, with free services being reserved for those who cannot provide for their own healthcare (or other) cover.

3. A single fund?

It is not clear to SASCI how South Africa will move to a be a "single fund financing and purchasing all healthcare" (clause 3…). Clause 2(2) contradicts the single fund concept in that it states that all currently funding and functions stay as is. It refers explicitly to the Constitution, which grants provinces the power to deliver healthcare, and the right to obtaining funding from the National Treasury for it. This is another hope that is raised amongst patients, the general public and health officials, namely that because of central fund, the inefficiencies and challenges experienced by provinces will be overcome. This will however not be possible for as long as clause 2(2) is in existence, and until the constitutional provisions that give provinces certain rights, are changed.

If the NHI is unable to tap into funds allocated to provinces, its resources must come from somewhere else. Clause 46(1) states that the Ministers of Health and Finance must "determine the budget and allocation of revenue to the NHI Fund on an annual basis". This is contradictory to the provisions of the PFMA and National Treasury Regulations relating to public entities, the allocation of revenue requires an appropriate to be made by vote of parliament and budgets to be set by the institution's accounting officer.

SASCI believes there are inconsistencies and outstanding legal matters relating to the NHI as a single fund, which should be addressed prior to the finalization of the Draft Bill for submission to Parliament.

[2] http://www.health.gov.za/index.php/component/phocadownload/category/383-national-health-insurance?download=2176:nhi-booklet; NHI Bill, clause 10(2)(b), clause 11(1), and clause 12(1) & (3).

[3] Sections 41 – 46 of the National Health Act, 2003.

The Davis Tax Committee ("DTC")[4] has analysed the funding shortfall of the NHI in the light of the current and envisaged future economic circumstances. The DTC's finding is definitive, namely that the NHI is not affordable, and increased taxation in whichever form, would be difficult if not impossible.

4. Accredited providers

The NHI Bill repeatedly refers to healthcare providers (professionals/practices and health facilities/establishments) must be accredited and certified:

- Accreditation is done by the NHI Fund, under clause 38, and
- Certification by the DG of Health under the National Health Act's ("NHA") certificate of need ("CON") provisions.[5]

The main change brought about by the schedule of other laws changed is that being accredited at the NHI Fund would be a criterion to obtain a CON. This means that, unless a provider is accredited by the NHI Fund, s/he or their practice or a health facility will not be able to practice. It would therefore be impossible for anyone to "opt out" of the NHI. It is understood that the NHI Fund would not want practitioners to opt out, but will the NHI guarantee and/or require of specialists in the private sector to see certain numbers of patients? Insofar as cardiologists would be able to still see medical scheme patients where schemes have not been prohibited to offer such benefits, how will practitioners plan their business so as to ensure continued sustainability?

There are several overlapping criteria between the CON and the NHI's accreditation, such as:

- The range of healthcare services to be rendered – in the NHI in clause 38(2)(b)(i) and the NHA's section 36(5)(b)(i); and
- Healthcare professionals in the facility – in the NHI in clause 38(2)(b)(ii) and in the NHA's section 36(5)(b)(ii).

This means that two different entities, namely the National Department of Health and the NHI Fund both would have some overlapping and therefore potentially conflicting criteria and assessment of compliance therewith.

The main challenge in relation to clause 38 is that it would first require implementation of section 36 of the NHA, which, in turn, requires regulations to be made, and a system to be put in place to certify all practices and all

[4] http://www.taxcom.org.za/mediacentre.html.
[5] Sections 36 – 39.

health establishments. Under clause 39 the Minister would have to publish criteria for accreditation, not as law, which would also have to be done prior to this clause being implemented.

The concerns in relation to the CON are well-known, and it has now been unimplemented since the NHA was passed in Parliament some 15 years ago. These regulations would have to be finalized prior to any progress being made on the NHI. The fact that, under the NHI Bill, health care services can be "specified" by the Minister "from time to time" introduces uncertainty into the system.

5. Who sets the benefits?

There are a few references in the NHI Bill as to what the benefits could be, in broad terms:

- "Comprehensive health *service* benefits" (clauses 7(1), 11(1) and 38(7)), which appears to be terminology similar to what is used in the Medical Schemes Amendment Bill, namely that services will be described as benefits, and not conditions. However, pre-payment will be done by the NHI to public sector facilities on the basis diagnosis-related groups (DRGs), will supposes that services are unlikely to rendered for conditions that have not been factored into the DRG calculations.
- Measures must be taken for the funding for "primary, secondary, tertiary and quaternary levels of health care" (clause 5(1)(g)). Only insofar as primary care is concerned, does the Bill provide some details as to at which levels and how such services will be rendered as NHI benefits.

There are also no indications that the NHI Bill will "progressively', i.e. over time, increase access to health care, within "available resources", as it is required by the Constitution.

At present no-one knows what the content of the NH benefits will be, or according to which criteria it will be determined. Knowing what the NHI benefits would be would be critical for practitioners, and also for patients, in particular as section 34(4) of the Medical Schemes Amendment Bill proposes that the Registrar and the Minister of Health could prohibit medical schemes from covering NHI benefits, to prevent duplication.

The Benefits Advisory Committee ("BAC") (clause 25) will "set and review", and not only just advise the NHI Fund, on the "health service benefits" and "types of services to be reimbursed". However, the Minister is not under any duty to appoint a BAC – he "may" do so. If the Minister does not do so – who would set these "benefits" and determine the "types of services" to be reimbursed?

The BAC must also determine the treatment guidelines to be used taking "into account … new technologies". SASCI is of the strong view that treatment guidelines must be set in accordance with the principles of evidence-based medicine, and by persons duly registered, trained, skilled and adequately experienced to set such guidelines. These Guidelines cannot be set by negotiation, it must be set on scientific grounds.

The BAC must consider, but not set, treatment guidelines, the same as they would consider other factors, such as burden of disease (nationally, but also with regional variations), healthcare needs, the outcomes of health technology assessments, developments in medical practice, etc.

It is unclear why the BAC includes two representatives from HASA, and no other professional grouping or trade association. SASCI recommends that the BAC, as per the specific specialty they are dealing with in terms of benefits, involve at least two representatives from that professional society, so as to ensure that evidence-bed medicine is considered.

6. Price regulation and reimbursement?

The public sector will get budgets on the basis of DRGs from the NHI Fund, and primary care providers will be paid a risk-adjusted capitated fee from primary care authorities per district.

The Bill contains three pointers, but nothing clear, on how private sector providers could receive payment from the NHI Fund:

- Price-determination "annually after consultation with" providers;
- "All-inclusive fee", based on performance, for specialist and hospital services;
- Reimbursement;
- Payment mechanisms yet to be determined.

None of these concepts are defined, or are delineated by criteria as to how such each of these broad powers will be exercised, or how, if provided for, regulations must be framed. remuneration forms will be used. For example, price-determination will take place. Why would this be necessary if up-front payments are made by the NHI Fund? On what will these consultations be based? Practice viability and sustainability must be considered, to avoid the rocky road the pharmacists' fees have been one for the past 15 years, and to avoid legal challenges. If done, how will the previous difficulties with pricing be overcome? Why is the HMI-proposed model of price negotiation facilitated by an independent entity (the Supply Side Regulatory for Health) not considered? Consultation with professionals would mean consultation with societies. This cannot occur without the Competition Commission granting exemption for such societies. It is noted that the schedule to the Bill proposes that the Competition Act be amended to exclude "the operations of the NHI Fund" from the Competition Act. However, mechanisms of price-determination and/or negotiations would necessitate an exemption from the Competition Act also for professional societies. Furthermore, exempting the "operations of the Fund", may be construed as the Fund not having to consider the competition effects of its decisions, and may even be construed to permit collusive tendering.

It is also not clear what an "all-inclusive fee" means? If referring to global fee or other alternative reimbursement models, the HPCSA prohibitions in this regard must be addressed first. Measures must also be taken to prevent the plethora of concerns in relation to global fees as listed in the HMI report. There is also a risk that professional healthcare services could be corporatised – as already the case with the tenders issued for cataracts, arthroplasty and oncology. Hospitals and medical scheme administrators will offer these services, including those of the healthcare professionals, at an "all-inclusive fee". In these fees, as providers will be sharing the risk of having to treat the patient within those limits, providers should have the choice of medicines and medical devices used.

In some places in the Bill refers to the "reimbursement" of services in terms similar to what one would have expected of a medical scheme, or the RAF, or Compensation Fund. However, the NHI would be a pre-payment system where claims are not made against the NHI Fund.

In terms of the "payment mechanisms", clause 39(1) says that these will be "determined" by the Minister. The word "prescribed" (i.e. by regulations and therefore in law), is not used. However, clause 52(1)(b) states that the payment mechanisms will be determined by regulations. However, there is no empowering framework against which the lawfulness, or not, of such payment mechanisms could be adjudicated. SASCI proposes the following criteria to be included, for payment mechanisms, which should be based on -

- Ensuring the availability of healthcare services by securing the viability and sustainability of the provider's practice or health establishment, as the case may be;
- The cost of capital equipment (medical devices) required to treat a patient;
- The cost of consumables, disposables and implants:
- Demographic and epidemiological information of the patient population served;
- Operating costs;
- Staff costs, including the salaries of professional staff;
- Training and set-up costs;
- Etc.

The cost-base for a private provider (healthcare professional and health establishment) are vastly different to that of the public sector, with facilities not being subject to loans or rental, differences on capital equipment (medical device) costs, etc.

It is noted that in relation to payment of providers, the phrase "personal health services" is used, which is not defined.

7. Medical devices and medicines

Interventional cardiology relies on access to devices of good quality, and medicines that address the severity of cardiovascular conditions, and prevent or avoid further harm. SASCI is concerned that a system of centralized

procurement will lead to unintended consequences, such as that consumables, disposables and implants will be procured that do not fit the range of capital equipment currently in the public sector.

For the private sector, an all-inclusive fee must ensure that the devices in that facility or practice, is able to be used effectively, and such products cannot be excluded from the NHI Fund on the basis of a centralized procurement decision.

In both sectors consignment stock is vital, so as to ensure that patients receive the right implant, for example. This cannot be evaluated or set up front, and is patient-specific. A model that includes provision for consignment stock does not sit well with centralized procurement models.

Although SASCI supports health technology assessment, this function cannot be situated within the NHI Fund. Once again, the recommendations by the HMI is illustrative. As is the case with the UK's NICE, or other bodies, HTA must be undertaken by an independent body. An HTA result is also not the only factor that will determine pricing and/or whether a particular product would be procured or not. Advice as to how HTA bodies are to be set up to be efficient, including being properly resourced with skills professionals, and not introduce delays in patients being able to access technologies.

Decisions relating to medicines and medical devices must be left to professionals within the budgets, DRGs or fee arrangements entered into. This will ensure that all patients can be treated effectively and appropriately. This will also address issues experienced by patients with treatment failure or adverse events (e.g. on warfarin), thereby allowing all patients to be appropriately and adequately treated.

The imposition of stock-standard formularies and device lists means that the most vulnerable patients, i.e. those with complex disease, co-morbidities and who have inadequate treatment responses, cannot be appropriately treated. If the all-inclusive fee holds providers accountable for performance (i.e. outcomes), practitioners should have good arsenal of products to ensure patient-appropriate treatment.

SASCI notes that the correct definitions of medical devices and in vitro diagnostics have not been provided in the Bill and proposes that definitions align with the Medicines and Related Substances Act, 1965, in terms of which such products are governed. The definitions "health goods" and "health-related product" must therefore be removed. A definition to denote products that are not medicines, medical devices or IVDs, must be found to cover all other types of goods that may be required by the NHI Fund (e.g. furniture and non-device capex, etc.)

8. Other concerns

Apart from the above, SASCI is also concerned about the following:

- It seems that providers would have to take on the task of registering NHI beneficiaries. It is unclear how exactly this will take place, who will have access to such registration database, who will carry the cost of such registration, and verification, activities, etc. (clause 8(1)).

- SASCI is also concerned that the NHI-database will be captured by corporate interests, as data must be "compiled and stored by an independent data company" (clause 34(2)). It also notes that the Protection of Personal Information Act, 2013, does not appear in the Bill at all, only the Promotion of Access to Information Act, 2000. Both laws pertain to the NHI Fund and its activities.

- The limitations placed on who could be beneficiaries of the NHI (clause 7), namely only citizens and permanent residents, although acceptable on paper, and although this was possible to implement in the social grants system, would not work under the NHI.
    - If a patient has an emergency cardiac event, such a patient will be treated. Afterwards, no facility or healthcare provider will put that person on the street. This means that, irrespective of the NHI criteria, the reality is that both the private and public sectors would have to have mechanisms in place to bill such patients, and to recover such monies owed.
    - All persons, constitutionally, have the right of access to healthcare, and the absolute right to emergency care. The Bill now affords emergency care only to refugees and asylum seekers. Such persons would also have access to services for "notifiable conditions" (and it must be noted here that HIV is not a notifiable condition in South Africa).
- SASCI's members have already experienced the difficulties in obtaining malpractice cover if they work in both the public and private sectors. Such indemnification becomes even more important if NHI patients are required to be seen only in strict adherence to NHI protocols (ito systems and referrals) and treatment guidelines, etc. Where harm is caused as a result of this adherence, the NHI should cover the cost of malpractice insurance / indemnity cover.

9. Conclusion

SASCI believes that a lot more work and consultation, in particular on the pre-conditions for the NHI, is required. These consultations cannot take the form of large gatherings where various speakers address, and, bluntly put, promote the NHI. The consultations must be in the form of interactive workshop, so as to address the practicality of implementing a system that will, in the end, lead to greater access to better healthcare services for all.

SASCI PPC can be contacted through

Mr George Nel

SASCI Executive

083 458 5954 T

sasci@sasci.co.za

www.sasci.co.za