SASCI
South African Society of Cardiovascular Intervention

SASCI Submission (29 Nov 2019) to Parliament pertaining to the National Health Insurance Bill No 11 of 2019

Cardiovascular Disease (CVD) is the leading cause of death in South Africa after HIV/AIDS. More South Africans die of CVD than of all the cancers combined. CVD is responsible for almost 1 in 6 deaths (17.3%) in South Africa. Approximately 215 people die every day from heart disease or strokes. Every hour in South Africa, 5 people have heart attacks, 10 people have strokes and of those events, 10 people will die from it.

There are about 200 registered cardiologists in the country of about 160 in active practice. This represents a ratio of three cardiologists per million population. To put that into context, the average country in European Union has average of 200 cardiologists per million population. South Africa is woefully short with >40% of practising cardiologists reaching retirement age within the next 15 years. Despite this, the South African cardiology community have maintained standards of excellence equivalent to the best in the world with many becoming frequent faculty guests and participants in the major conferences of Europe, USA and elsewhere.

The South African Heart Association is the official professional body recognised by the HPCSA and comprises a number of subspecialty interest groups within this specialty. South African Society of Cardiovascular Intervention (SASCI are affiliated as a Special Interest Group with the SA Heart Association) represents cardiologists with a particular interest and activity in interventional cardiology which deals with invasive vascular procedures to open obstructive and diseased coronary and peripheral arteries. This technology is potentially lifesaving in patients having a myocardial infarction (heart attack) and stroke, as well as improving life expectancy and quality of life in many other patients. Although many other health professionals are involved in the fight against cardiovascular disease cardiologists remain the cornerstone of diagnosis and treatment of these patients. Therefore any analysis of needs and resources must take into account the availability and requirements of cardiologists in a national health service.

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). The society is also a key enabler of CPD accredited education and training in interventional cardiology.

SASCI Educational initiatives are a cornerstone activity during training and after graduation of cardiologists. Highlights of the educational initiatives SASCI has been and continues to be involved in:

- **Master the Complex 2019**

SASCI and PASCAR was involved in the Master the Complex Meeting 2019 rendition in Johannesburg on 25 and 26 January 2019. This year, 60 cardiologists attended the meeting including delegates from South Africa, Mauritius, Kenya, Sudan and Namibia. Drs Simon Walsh and Julian Strange featured as the international faculty and was supported by well-respected South African and Sub-Saharan African interventional cardiologists. The program was developed under the guidance of Dave Kettles (RSA), Farrel Hellig (RSA) and Awad Mohamed (Sudan). The meeting provided cardiologists with training on new trends in complex interventional procedures, technologies and troubleshooting through interactive talks and live cases.

- **STEMI Africa Live! 2019**

SASCI and PASCAR supported the development of African Cardiology in Nairobi, 26 to 27 April 2019 with Dave Kettles, Adie Horak and Justiaan Swanelvelder as part of the South African faculty and Zimasa Jama (Groote Schuur Hospital) as case presenter.

- **EuroPCR 2019**

SASCI with support from Medtronic and Boston Scientific ensured that cardiologist on faculty received educational grants. The recipients were Arthur Mutyaba, Jens Hitzeroth, Michael Dean and Marshall Heradien.

- **Endovascular Cardiac Complications Congress 2019**

ECC 2019 was held in Lausanne, Switzerland from 26 June to 28 June. Dave Kettles represented SASCI, giving a keynote lecture during the congress.

- **SASCI VPP**

The SASCI Visiting Professor Program is a well-established initiative and a highlight of the SASCI calendar annually. Prof Simon Redwood, professor of interventional cardiology and honorary consultant cardiologist at Guy's and St Thomas' NHS Foundation Trust, has accepted our invitation to travel to South Africa as the Visiting Professor for 2019.

Prof Redwood payed visits to the Gauteng and Free State Medical Schools during the month of July 2019 and will be back in South Africa from 30 September 2019 to 2 November 2019 to attend the SA Heart conference, AfricaPCR course and visit the coastal Medical Schools. Prof Redwood works hands-on in the cath lab with the fellows and consultants, supported by multiple lectures at each unit. The SA Heart

Branch and SASCI Evening Lectures initiative is also a great success attracting Bloemfontein (52), Johannesburg (52) and Pretoria (57) delegates.

We look forward to welcoming Dr Greg Barsness from the Mayo Clinic, Rochester, USA who accepted our invitation to travel to South Africa as the Visiting Professor in February and March 2020.

- **Annual Fellows Workshop**

SASCI hosted the 15th Annual Fellows Workshop in Sandton on 17 and 18 August 2019. The meeting was a great success with interactive and robust discussions and debate between the faculty and fellows. A total of 48 practitioners attended the Workshop including 2 from Kenya and 2 from Mauritius. We hope to expand our SSA delegate continent in 2020 and make this a truly African Fellows training and networking event.

Jean Vorster and Graham Cassel again took the lead and developed an exceptional program that was well supported by an extensive faculty including Gavin Angel, Dave Kettles, Sajidah Khan, Adie Horak, Farrel Hellig, Ahmed Vachiat, Jacques van Wyk, Mark Abelson, Chris Zambakides and Pieter van Wyk. James Fortein (UFS) and Hanneke Dannheimer (WITS) won the best-case presenter's award and received free registration to attend the AfricaPCR Congress 2019, sponsored by SASCI.

- **RC Fraser International Fellowship**

For the past 6 years SASCI send Cardiology Fellows to Prof Simon Redwood unit at Guy's and St Thomas' Hospital, London for one-month training. The 2019 incumbent is Dr George Harris (UFS) and Dr Karim Hassan (US) for 2020.

- **TCT 2019**

Transcatheter Cardiovascular Therapeutics (TCT) is a big American meeting with a very big reputation. Under convenorship of Graham Cassel, Drs Sajidah Khan, Mfundo Mathenjwa and Mpho Sebesho will also be attending, SASCI is happy to once again support a group of RSA Cardiologists.

- **AfricaPCR 2019 (offered Jointly with PASCAR and SA Heart Congress 2019)**

In 2018, SASCI supported 59 delegates to attend AfricaPCR including 24 Fellows and saw total grants increase to 79 in 2019.

- **Fellows Course at Columbia University NYC**

In 2018, SASCI selected three fellows to attend the Medtronic Fellows Course at Columbia University New York City for the first time. They were Kwena Komape-Makgato (Chris Hani Baragwanath Academic Hospital), Menachem Levin (Charlotte Maxeke Johannesburg Academic Hospital and Deya Ramachandran (Inkosi Albert Luthuli Central Hospital). The next Course will take place from 7 to 9 February 2020 in New York, USA.

- **STEMI SA**

Dr Adrian Snyders and Prof Rhena Delport have done a huge amount of work for this project. Data collection for a national registry has just started at Life St Dominic's Hospital and is about to start at a number of other hospitals. We are wanting to capture a cross section of current management of STEMI and provide that data that everybody always notes 'does not exist'. Educational Workshops have and will continue to be arranged to assist those who wish to strengthen STEMI care through enhanced First Medical Contact (FMC) in their region.

- **Proctorship Program in 2019 - SASCI Visiting Expert Program(s)**

SASCI in partnership with Vertice Healthcare launched a new Visiting Expert Program with a focus on proctorship in Complex PCI procedures. Prof Tony Gershlick, consultant Cardiologist at Leicester's Hospitals and Honorary Professor of Interventional Cardiology at the University of Leicester was the first Visiting Expert (and travel to South Africa in November 2019). Prof Gershlick performed hands-on proctorship of cases as they present on the day with a focus on bifurcation and other complex PCI procedures. We hope this initiative will become an annual program. The next proctor Prof William Lombardi (Seattle, USA) is due in South Africa mid-January 2020.

- **Society for Cardiovascular Angiography and Interventions Fall Fellows Course**

With support from SCAI and Boston Scientific, SASCI supported four South African fellows to attend the SCAI Fall Fellows course in December 2018 (Aveen Mahabal, Robert Leibbrandt, Mmuso Mogwera and Absalom Nkosi). The seven 2019 recipients are Ndikondisene Tshiovhe, Ashandren Naicker, Zimasa Jama, James Fortein, Jerry Chen, Mogobe David Mashilo and Menachem Levin. They will travel to USA in December 2019 for a week's training.

Cardiovascular disease is the leading non-communicable cause of death in South Africa, and contributes significantly to morbidity.[1] The way in which the NHI is structured, what benefits it provides, and how funding works will therefore have a direct impact on the cardiovascular health of all in South Africa.

Please find below SASCI's submission on the Bill.

[1]See, for example: http://www.heartfoundation.co.za/wp-content/uploads/2017/10/CVD-Stats-Reference-Document-2016-FOR-MEDIA-1.pdf; https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30476-5/fulltext; http://www.uct.ac.za/sites/default/files/image_tool/images/292/Publications/Cardiovasc.pdf; etc.

As part of engaging its membership, SASCI[2] undertook a **survey** on key aspects of the Bill, and the results of the survey is included in the comments below. Our survey also gives a snapshot of our members: 40% of respondents have been in practice for more than 11 years, which show the vulnerability of our specialty with less than 13% having being practicing for less than 5 years. 67.50% are only working in the **private sector** and some 15% of respondents also working ***pro bono*** **in the public sector**, and another 7,5% undertaking paid work in the public sector. The bulk of the respondents 47.5% are working in the Gauteng province, with 25% and 22,5% in the Western Cape and KZN respectively. What is concerning is that more than 78% of respondents in the **public sector** reported that there were no posts for cardiologists and where there were (11% in respondents), those posts were not filled. No respondent reported that there were posts but no persons to fill them. This indicates the extreme urgency with which human resource challenges in the public sector must be tackled prior to rising expectations in terms of healthcare service delivery under the NHI. The previous Human Resource for Health Policy ended in 2017,[3] and no or limited progress seems to have been made.

1. A path to Universal Health Coverage; set by the Constitution, 1996

1.1. SASCI supports the objective of achieving an **equitable, sustainable healthcare system**. SASCI acknowledges that there have been historical inequalities and exclusions regarding access to healthcare for all which this bill seeks to address, and having members in both the public- and private sectors, can attest to the shortcomings in the health sector. The achievement of the objective of access to funded healthcare services for all, includes reforms in both sectors, some of which have been long-outstanding, such as the promulgation of human resource standards in terms of section

1.2. Whilst the Bill is a litany of **inconsistences**,[4] and fails to set principles according to which health care rights could be lawfully limited during the process of roll-out of progressive benefits over time, political pressure, and the expectations of the public - as became apparent during the provincial hearings the past few months - is mounting. This should, however, not lead to the adoption of a Bill that may, in the end, face numerous challenges, or lead to uncertainty affecting healthcare practices and businesses, or unrealistic expectations from the public. Our submission aims to point out where these risks lie in the Bill.

1.3. Although officials working on the NHI project have given assurances that the NHI will only act within what is affordable, and there is time for consultation, **the wording of the Bill** is, and will

[2] Through an independent third party supplier to ensure compliance with competition law.
[3] https://www.gov.za/sites/default/files/gcis_document/201409/hrhstrategy0.pdf.
[4] E.g. it states in section 3(4) that it does nohttps://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30476-5/fulltextt change the functions or funding of organs of state, but does exactly that in relation to the public hospitals, and in particular central and tertiary hospitals, where many of SASCI's members are active (sections 32(2) and 35(2)).

remain the only legally binding framework to the NHI. Therefore, where wording states, for example, a system of *price-setting*[5] by the NHI Fund, whilst officials indicate a desire to implement the findings of the Health Market Inquiry (HMI) in establishing a *price negotiation* mechanism, one would expect that the NHI Bill wording be amended to align with the HMI recommendations.

1.4. Section 27 of the Constitution of the Republic of South Africa, 1996 ("the Constitution") guarantees everyone the **right of access to healthcare services** and the **right of access to social security** (i.e. financial safety-nets in cases where persons cannot cover the costs of, in this case, ill health). Of paramount importance is that section 27 demands that there be progressive realization of healthcare, to be undertaken through reasonable measures, and within available resources.

1.5. Although the Bill recognises its roots in section 27, the application of the principles of "reasonable" measures, "available resources" and "progressive realization" is virtually absent in the text. This means that, for example, where strict adherence to a **treatment pathway** is required, and this limits the rights of a patient with co-morbidities, there are no criteria against which compliance with such pathways could be deemed to be acceptable and hence constitutionally defensible. Sections 8(2)(b) and 39(2)(b)(iv) requires **absolute and unwavering adherence** to these pathways by both providers and patients, with no criteria as to how to evaluate when such adherence may be unreasonable.[6]

1.6. This aspect obviously also raises the issue of **medico-legal liability** – if adherence to NHI criteria leads to harm, who would be legally liable? Will the NHI cover the cost of medico-legal insurance, or would that rests on an individual? Has any investigations being done as to whether insurance companies would cover this risk – in SASCI's experience private sector practitioners working *pro bono* or for a fee (see percentages of respondent-members affected by this above), in the public sector are not covered by their insurers.

1.7. Apart from section 27, SASCI is cognizant of other constitutional issues which may arise regarding the Bill. Currently ambulance services, in terms of the Constitution, fall within the exclusive jurisdiction of the Provinces. The Bill however defines "emergency services" in section 1 as inclusive of ambulance services and only provide for one payment mechanism for such services in section 41(3)(c). As with the change to the hospitals position within provinces, now being proposed to be "national components of government"[7] and "autonomous legal entities"[8]

[5] Section 10(1)(g), namely the NHI Fund will "determine payment rates annually … in the prescribed manner".
[6] This matter was already before the Constitutional Court *in Oppelt v Western Cape Department of Health*, 2015, http://www.saflii.org/za/cases/ZACC/2015/33.pdf.
[7] Section 7(2)(f)(i).
[8] Section 32(2)(b).

or "semi-autonomous"[9], their functions and funding seem to be changed under the Bill without a concomitant change amending the empowering provision, being the Constitution itself. The move of central and tertiary hospitals from provinces to the national government will affect many of SASCI members as employees of such provinces, as well as their roles in academia, including training and research. This matter is obviously of grave concern to SASCI, as **moving of employment has labour law implications**, and **research and training will be affected** as products available at provincial level may not be so at national level. It is impractical to impose equality on levels of research, service and expertise on service providers.

1.8. Furthermore, section 217 of the Constitution obligates competitive bidding, yet the Bill explicitly excludes the Competition Act from its provisions and sets price-determination as a principle for healthcare professionals[10] and for medicines[11]. Section 217 gives rise to the Public Finance Management Act and the National Treasury Regulations relating to procurement and it is unclear how such a system could, legally and constitutionally so, be reconcilable with a system of price setting.

1.9. **SASCI unequivocal supports a price negotiation system**, along the lines as proposed by the HMI, which do not require wholesale exclusion of the Competition Act, and would urge its urgent implementation as a necessary precursor to the NHI. Through that, the text in the Bill relating to "price and payment determination", "payment rates", etc. must be replaced with terminology denoting a system of price negotiation, as well as mechanisms of alternative reimbursement (such as per event fees, such as those with which SASCI has been involved), and payment mechanisms in which health outcomes and risk-sharing are appropriately rewarded. However, these negotiations cannot be, as section 11 (2)(e) to "the lowest possible price". Apart from contradicting other sections in the Bill referring to price setting, does not explain how this lowest possible price would be arrived at, and how/when the "the lowest" price would be obtained.

1.10. Whereas the Constitution requires **progressive realization** of health and social security rights, propose changes such as the change in control over central and tertiary hospitals, the prohibition on medical schemes to provide cover in parallel to the NHI, the inevitable limitation brought about by the NHI Formularies and a national standardization of care through procurement and national pathways, will lead to **health care potentially being reduced for some patients**. Patients with rare diseases that could have cardiological impact, such as Fabry's disease, could be worse off under the NHI system. Patients in some, but not all of the central

[9] Section 7(2)(f)(iii) – the difference between "autonomous" and "semi-autonomous" is not clear, neither is its meaning in law. Are these now independent government entities (i.e. of same status as, for example, the MRC or SAHPRA), with powers afforded to act independently (e.g. on procurement and to issue tenders independently) and be held independently accountable.
[10] Sections 10(1)(g), 41(1), 41(3)(b), 41(4) and 55(1)(b).
[11] See Schedule to the Bill proposing to amend section 22G of the Medicines Act.

hospitals also have access to TAVI, which would be at risk under the new, national system. As healthcare professionals, SASCI's members are also individually accountable for treatment decisions, including the denial of care.

1.11. Lastly, the **renewed efforts to engage stakeholders** on the Bill seems too late, as the Bill is now, with the final wording proposed by the National Department, before Parliament. The change for negotiations on the Bill is passed. Therefore, the various initiatives currently underway to engage, seem futile, as there is no avenue for the Department to introduce any newer, negotiated version into Parliament.

1.12. We also note the **absence of key consultations** from those listed in the Memorandum to the Bill (paragraph 7), with entities directly affected by the Bill. Notwithstanding this lack of consultation, the Bill then, seemingly without consultation, proposes changes to legislation under the control of such other entities. These include, amongst others:

1.12.1. The RAF (Department of Transport);
1.12.2. The Compensation Commission (i.e. the Department of Labour);
1.12.3. The Competition Commission and the Department of Trade and Industry;
1.12.4. The Department of Science and Technology and Higher Education (due to the impact on universities and central and tertiary (academic) hospitals – research and training);
1.12.5. The HPCSA and other statutory bodies as amendments to the Health Professions Act are proposed and more changes are required through provisions in the Bill, currently legally impossible, for example, such as multi-disciplinary practices[12] and shared payments[13];
1.12.6. The Department of Justice on the creation of a Tribunal with the status of a High Court;[14]
1.12.7. The Information Regulator on the personal- and special-protected information categories of in particular health and children.[15]

2. About our comments

2.1. Whilst an attempt has been made to comment on the Bill in its entirety, an omission to comment on any provision does not amount to an acceptance of that provision. We have singled out provisions that specifically impact SASCI as a society and its members. In other words, this comment should not be construed as constituting a closed list of reservations with the Bill.

[12] Section 1, definition of "primary health care".
[13] Sections 41(3)(a) – subcontracting as is prohibited by HPCSA Ethical Rule 18, and 41(3)(b) – payment of all all-inclusive fee that incorporates unregistered entities (hospitals) and registered entities (cardiologists, for example).
[14] Section 45.
[15] Sections 6(m), 11(1)(l), 21(1), 34, 39(2)(v) and (5), 40 and in particular subsections 40(2), (4) and (6).

2.2. SASCI agrees with the introductory part of the Bill stating the purpose, aims and justifications of the Bill. The preamble references the constitutional notion of available resources. There however has been **no costing model** to quantify the available resources. SASCI is concerned with the uncertainty surrounding the issue of cost of achieving the universal health coverage in the absence of such a costing model, and in the light of the report issued on the NHI by the Davis Commission (based on the 2017 White Paper, on which the current Bill is based) and the most recent findings of the National Treasury, dated 30 October 2019, that **the 2017 White Paper version of the NHI is no longer financially feasible**.

3. Comments on specific sections of the Bill

Section 1: Definitions

3.1. Various terms in the Bill are not defined, that should be defined e.g. personal and non-personal health services and definitions that are not clear, e.g. "complementary cover" versus reference in section 7 on "complementary lists". In addition, the word quality is not defined in the definition of quality of care, an aspect that falls under the jurisdiction of the OHSC and health products regulatory authorities, such as SAHPRA and Radiation Control. A definition should therefore not create a secondary system of quality control, but leverage existing structures and the definitions used by them, as indicators of quality.

3.2. The definitions of "health goods" and "health-related product" are confusing and contradict the definitions found in the Medicines and Relates Substances Act, specifically for medical devices (where equipment and supplies are not separate from "medical devices") and in vitro diagnostics (IVDs). The Bill also, by inclusion, excludes the procurement of non-health goods that may have to be procured under the NHI system, such as furniture, vehicles, generators, IT equipment, meals for patients, etc. SASCI proposes that the two definitions be reconciled to produce one definition for purposes of certainty. SASCI supports the inclusion of a new definition of "health products", as inclusive medicines, medical devices and IVDs as per the Medicines Act, and inclusive of foods for special medical purposes, as well as disinfectants that fall under the Foodstuff, Cosmetics and Disinfectants Act. Health research is also not classified as a "health good".

Section 2: Purpose of the Bill

3.3. The stated purpose of the Bill includes funding of the NHI through mandated prepayment. This provision seems to have been lifted from the as of yet-unpublished Money Bill and the NHI Bill cannot levy or empowering the levying of any pre-payments. The Fund further seeks, through this Bill, to ensure the equitable and fair distribution of services. This function falls within the exclusive jurisdiction of the National Department of Health (NDOH) as empowered by the

National Health Act. In doing this, the NHI Bill violates the principle stated in its Memorandum of a purchaser – provider split.[16] It is the role of the NDOH to govern health service provision, and this cannot be done by means of the NHI Bill, as it would violate this principle.

3.4. Insofar as the Bill requires even of unaccredited establishments to maintain a register of users, it exceeds its purpose and mandate. To regulate provider conduct in general, the provisions of the NHA, and in this regard relating to health information, have never implemented and no regulations created.

Section 3: Application of the Bill

3.5. The Bill provides a general override of other laws and bodies with constitutionally allocated jurisdictions. Of particular note is the Children's Act (the Bill only gives effect to "basic" health rights of children), the Protection of Personal Information Act (the Bill extracts some, but not all of the grounds for sharing and utilisation of personal information), Health Professionals Act (e.g. the Bill authorises contraventions of the HPA), National Health Act (e.g. on free care and the obligation to give patients choices as part of the process of informed consent), Consumer Protection Act (which e.g. sets obligations on information to be provided to consumers), etc.

Coverage

3.6. Exclusion of categories of people who are in South Africa through illegal means might open it up to a constitutional challenge. Section 27 (1) of the constitution states that "*everyone*" has a right to access to healthcare services including reproductive care. Section 27(3) of the Constitution supports emergency care. Whereas a line had been drawn in relation to social grants (a form of social assistance under the principle of social security in section 27) between citizens and residents to such grants, the courts may view access to health care differently.

3.7. SASCI's members is concerned that the decision to turn away illegal foreigners be placed on providers. Only notifiable conditions[17] and emergency services can be attended to, in terms of section 4(2) of the Bill. To limit access to healthcare to this category of patients may on the surface appear as a cost-saving measure but it could in the long run be counter-productive. Turning away a moderately sick person until he is seriously sick and the situation has deteriorated to any emergency, can never be a prudent strategy as emergency situations invariably involve detaining a patient and using ICU- and expensive life support technology.

[16] At paragraphs 2.1.2 and 2.2.3.

[17] Listed in R.2438 of 30 October 1987 and as amended by R.485 of 23 April 1999, and include: Acquired immunodeficiency syndrome (AIDS); Chicken pox; Cholera Diptheria; Epidemic typhus; German measles (rubella); Haemorrhagic fever diseases of Africa; Haemorrhagic virus conjunctivitis; Hepatitis A; Leprosy; Louse infestation; Measles; Meningococcemia; Mumps; Plague; Poliomyelitis; Scabies; Tuberculosis of the lungs; Typhoid fever; Whooping cough. Given that mumps vaccine is not on the government vaccines list, the EPI, the inclusion in this list, is noteworthy.

3.8. The Minister is given powers to exercise unfettered discretion without providing the criteria which must guide him. This constitutes an unauthorized delegation of legislative power.

User Registration

3.9. Section 5(1) of the Bill implies that all eligible persons must register and have no option to opt out of the registration. Unaccredited health establishments are also required to maintain a register of users in terms of section 5(7) of the Bill. Registration entails not only listing of a user, but also the collection of biometric data (e.g. fingerprints) and photographs (section 5(5)). In this regard, SASCI asked its members as to the IT equipment in their practices or in health facilities, only a fifth of respondents felt that their IT equipment would be able to handle a system requiring biometrics and uploading of photographs, with close to 53% not knowing if their systems would be able to handle this. 70% of respondents said they had a reliable internet connection. One respondent stated that at the public sector facility where s/he works, there are no computer equipment whatsoever.

3.10. The information that will be stored in this register, including health information that would have to be recorded and accessed by "health care service providers" under section 6(m), and which will form part of the NHA's section 74 (under which no regulations have yet been promulgated). Access protocols, provisions for patient consent and the general terms and conditions of use of the database would have to be stipulated in a principled fashion in the Bill, and access and consents logged for audit purposes.

3.11. The Minister of Health has the discretion to set the criteria of registration of foreign nationals in terms of section 5(6) of the Bill, with no framework as to how that discretion is to be exercised.

Accreditation

3.12. In terms of section 39 of the Bill, the position seems to be that, the NHI Fund will be responsible for accrediting providers that will be providing health service benefits in the NHI benefits package and who will be paid by the fund for that service.

3.13. Most public healthcare facilities currently do not meet OHSC standards and this is something that will leave many public sector facilities unable to contract with NHI should current OHSC standards be enforced. It is not clear by when the OHSC would have inspected all facilities and SASCI notes that there has been no engagement as part of the pre-work of the Bill with the OHSC as recorded in paragraph 7 of the Memorandum to the Bill. Without such accreditation

the NHI Fund would not be able to lawfully contract with any practitioner, practice of facility. It also appears that, at this stage, most public sector facilities do not pass the basic level of compliance with the standards set by the OHSC – and facility improvement plans and those timelines would dictate the pace of contracting. Most significantly – in terms of the funding model of the NHI, where the Fund provides budgets directly to hospitals and districts: if an entity does not comply, will such entity have to close down, or will that entity still get funding from the NHI through the Provincial Equitable Share.

3.14. A provider is required to be in possession of certification from the OHSC, meet the needs of users; appropriate number and mix of healthcare professionals; adherence to guidelines and referral pathways; adherence to national pricing; and submission of information to the national health information system. There is therefore a burdensome amount of activities to be done by a service provider prior to accreditation, but also an inability to comply – how, if one is not yet accredited and not in possession of such rules, does one prove compliance with referral pathways, treatment guidelines and the likes?

3.15. The accreditation provision seems to assume that all facilities would want to be accredited as such. The provision is also based on an assumption that there will be enough accredited entities. Therefore, the Bill is silent on what it is that would happen should there be a scarcity of providers. This again highlights the problem with the NHI Bill – first things, such as addressing the Human Resource for Health Policy, and issuing the necessary regulations under the National Health Act, have not been done.

3.16. The NHI Fund is empowered to be able to renew provider accreditation and may withdraw or refuse renewal of accreditation. Parameters should be set in the Bill on the circumstances upon which such action would be taken by the NHI Fund.

3.17. It seems that the system of accreditation will add significant, and in our view, unnecessary burdens on practitioners and on the NHI Fund. There are tens of thousands of healthcare practices that would require accreditation, and even the most basic of desk to assessments are bound to take years.

User Rights – necessary care?

3.18. Section 6 of the Bill applies in addition to rights elsewhere in other laws – "without derogating from any other right…" However, the rest of this very section implies various limitations to rights, either in terms of the treatment available, the care pathways, where such treatment is available, etc. The choice afforded by section 6 of the NHA, and recognised in the Patient Health Charter, will be limited and users under section 6(h) only have the right to make "reasonable"

decisions about their healthcare. Users will only have the right to received (and this is not clear) – either "necessary quality" care, or quality care that is "necessary".

3.19. It seems to mean that cover is confined to what is necessary, in spite of the definition and other references to "comprehensive" benefits. The term necessary also appears in sections 7(2)(c) on patient transfers and 7(4)(a) and 8(2)(b) as a reason to not cover the care. It is unclear how this would work in practice – if a patient did receive what is later established as "unnecessary care", will the budget in the case of a public facility be adjusted (section 35(2)), or, in the case of a private facility, will there be some reversal of the all-inclusive fee paid under section 41(3)(b)? SASCI proposes that benefits must be afforded in line with "evidence-based medicine", where conditions are added as funded by the NHI.

Grievance and Complaints Procedures

3.20. The Bill provides stakeholders with a grievance procedure wherein they can lodge their complaints and appeals against the Fund. The provision is dependent on expeditious resolution of such grievances. Certain aspects of the complaints like fraud, quality of care share overlapping jurisdictions with other entities like the criminal justice system and the Health Care Professional Councils. This is clearly problematic.

3.21. Complaints is also possible on anything or any aspect of healthcare, including suppliers of medicines and medical devices, and SASCI submits that the provisions relating to complaints and the Tribunal created is limited in its jurisdiction to matters not

3.22. Protection of Personal information Act is referred to in section 6(m) of the Bill. However, the provisions in the NHI Bill in terms of criteria are different from those of the Protection of Personal Information Act Provision. Some provisions extrapolated from the Protection of Personal Information Act and incorporated into the NHI lose some of their meaning.

Benefits

3.23. The Fund "in consultation with the Minister purchases" healthcare services which are "determined" by the Benefits Advisory Committee (BAC) (section 7(1)). It is impossible for the Minister to either sit in on all purchasing decisions, and/or to co-determine benefits with the BAC. This comes against the background that the Minister is a political leader who may, or may not, be endowed with medical or technical expertise.

3.24. The BAC, which will have to fulfil a rationing function, must be separate from the entity or entities that set Treatment Guidelines. These are professional activities, and must be

undertaken by healthcare professionals not only qualified, but also experienced, in the specific treatment modalities of specific conditions. The BAC must then base the benefits on these Guidelines, as well as other factors, such as value-for-money and the availability of resources (e.g. human and equipment) to provide such benefits.

3.25. SASCI's survey in relation to the treatment guidelines followed, showed that a 100% of respondents followed the European Society of Cardiology Guidelines, which have been adopted by local cardiology associations, such as SASCI. Only 2,5% were also following the NDOH Standard Treatment Guidelines attached to the Essential Medicines List and a few following the American Heart Association / American Stroke Association Guidelines. SASCI supports the setting of Treatment Guidelines by the profession, from which various funders could make appropriate treatment decisions.

3.26. According to which criteria the BAC will exercise its functions under section 25(5), as it is clear that the whole set of what would be "comprehensive health services" would not be affordable, is not set out. This means that the limitation of the rights of access to healthcare, and the funding thereof, will be ad hoc and not principled-based. For example, medical schemes cover conditions that are deemed to be "catastrophic" and leading to hospitalisation, whilst aiming to prevent patients from using public facilities without funding. Section 4 of the National Health Act, in contrast, set the criteria for benefits that would be provided for free (i.e. would be government-funded) at certain primary care interventions, and care for the elderly and disabled. Without criteria as to how benefits are to be limited, the NHI Fund and BAC will face constant challenges in relation to the justification for such limitation, even being compelled in each instances to provide "adequate reasons for the decision to refuse care" to each individual user (section 7(5)(d)).

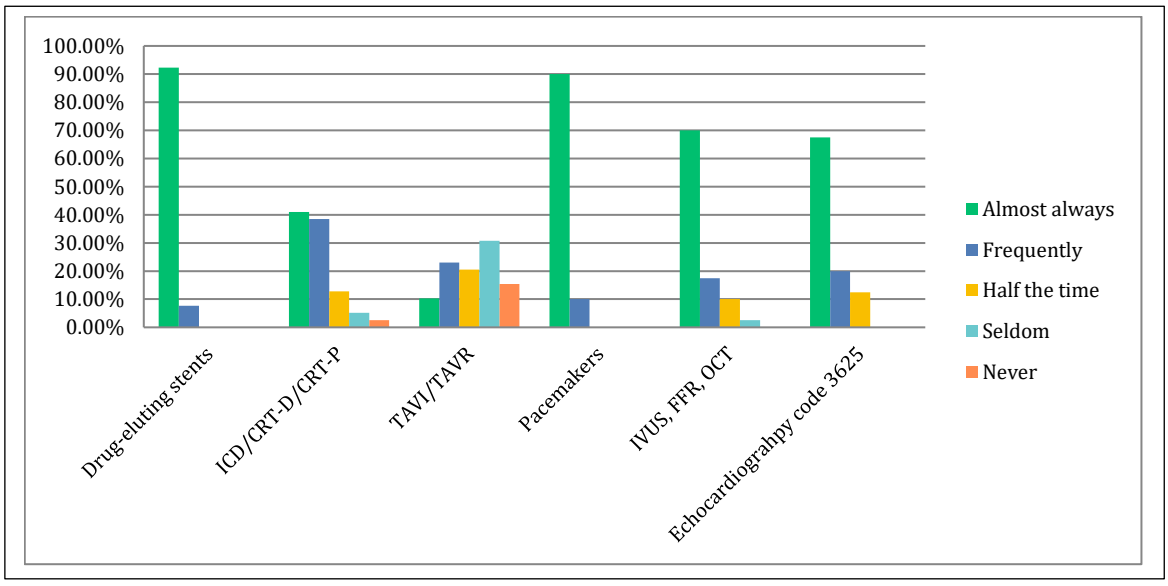
3.27. Where referral pathways are not adhered (section 7(2)(d)), the NHI will not cover the health care received. Read with the definition of complementary cover it seems that medical schemes may cover this excluded service then in terms of section 33 of the Bill, although such exclusion will not relate to the benefit itself, but rather to the process not being followed. So, section 33 would for example mean that if treatment by means of implantable cardioverter defibrillators (ICDs – used in patients with an irregular heartbeat), as a treatment option for patients at risk of sudden cardiac death is included in the NHI, medical schemes cannot offer this. However, if implanted, or implanted after not following the correct pathway, medical schemes would be able to fund this. The construct of preventing schemes from offering parallel benefits, whilst shifting users and providers that are non-compliant with NHI rules, does not make practical sense.

3.28. Clause 38(4) refers to Office of Health Products Procurement, which has to "support" the Benefits Advisory Committee in "developing" and "maintaining" a Formulary set on the basis of the Essential Medicines List (EML) and the Essential Equipment List (EEL). SASCI tested the use and awareness of these systems amongst its members in the survey. It showed that –

3.28.1. Of the top 5 medicines used by respondents, between 50 and 55% of respondents were unaware as to whether such medicines were available on the EML, with one respondent remarking that the EML was outdated;

3.28.2. The vast majority of practices own the equipment (ECG, echocardiography, Holter and treadmill with software) being used, meaning that any changes or inclusion, or exclusions, from the yet-to-be-developed EEL, will impact such practices, as the NHI Bill compels procurement only from the Formularies;

3.28.3. Key "tools" of the interventional cardiology trade, such as drug-eluting stents, pacemakers, IVUS/FFR/OCT and echocardiography are widely available to practitioners and patients, with ICDs/CRTs and TAVI so to a lesser extent (see graph below). This is important, as changes to the availability of these tools through the NHI Bill's benefits and/or formularies, will affect not only future care, but also continued care (e.g. some of the implantable devices require replacement after a certain lifespan, or require new batteries, for example.



3.29. Mention is made of complementary lists in terms of section 7(4) of the Bill, however there are no provisions under section 25 (in terms of which benefits are set), or section 38(4), in terms of

which formularies for medicines and medical devices are to be set, that gives further legal impetus to this option. Such complementary lists would be critical in cardiology, where patients often suffer from adverse effects or events, face potential harm (such as in the case of sudden cardiac death), or find that conventional therapy is not effective.

3.30. There are no exceptions to the formulary lists except for the possibility of undefined, unavailable complementary lists. Patients who do not respond to treatment that is available on the formulary lists, those who suffer harm as a result of having used these treatments and those who experience adverse effects of treatments on the formulary lists have not been catered or taken into consideration.

3.31. Whilst SASCI support the notion that medical devices and medicines must provide value-for-money, it is aware that, not all products can be taken through a formal Health Technology Assessment (HTA) process, and that practical considerations such as lack of data, skills and the time and cost-implications of HTA, must be considered.

The National Health Insurance Fund ("NHIF") and the powers of the Minister

3.32. The NHI Fund is established in accordance with Schedule 3A of the PFMA. Although the PFMS, and the associated Regulations by National Treasury imposes criteria in relation to how the NHIF must deal with its finances, there are no direct accountability provisions to Parliament by the Fund, or the Minister (given his/her extensive role in operational matters of the NHIF). The only reporting line to Parliament, as representative of the people, is by means of the CEO.

3.33. Not only does the Minister appoint all the Board members of the NHIF, its chairperson and CEO, s/he also appointments the Benefits Advisory Committee (BAC) and its chairperson, the Benefits Pricing Committee and its chairperson, and the Stakeholder Advisory Committee. The Minister is also empowered to, without limitation to that power, prescribe "additional functions" to the BAC (section 25(7)).

3.34. There is no limit to the term of office of the NHI Board. Section 13 (5) lists the required expertise of the Board members, however such expertise does not include clinical skills.

3.35. Furthermore, the Board is obligated to report to the Minister on any advice it gives to the CEO. Apart from the impracticality of this, it means that the Fund would not be independent, and would be beholden to the views expressed by the Minister in relation to such advice.

3.36. Senior staff are at risk of becoming political appointees – not the CEO, but the Board would appoint such staff. Given South Africa's most recent experiences in terms of "strategic" and

"political" technical and operational appointees at Schedule 3-entities, this configuration is rather to be avoided.

3.37. None of the key appointments to Boards, Committees or the CEO are made in public, or subject to public scrutiny.

3.38. Furthermore, the NHIF and its board is accountable to the Minister of Health (and not Parliament) in terms of sections 12 and 15(1). This clearly shows an absence of checks and balances – if the appointee is behold to, and also accountable to, the Minister, s/he would not challenge the Minister, and any lack of accountability would not be transparent, as there is a closed-loop in appointment and accountability.

3.39. The Minister of Health is empowered under section 55 (3)b to publish and finalize regulations without public consultations if the Minister of Health deems it to be in the public interest. This violates the Constitution's rule of law provision, and amounts to unfettered legislative power exercised by the executive. A similar problematic provision is section 56, that gives the Fund law-making powers through the so-called "Directives". The NHIF should, just like any other entity operating under the executive branch of government, act under the principle of lawfulness and legality, and not be law-making itself.

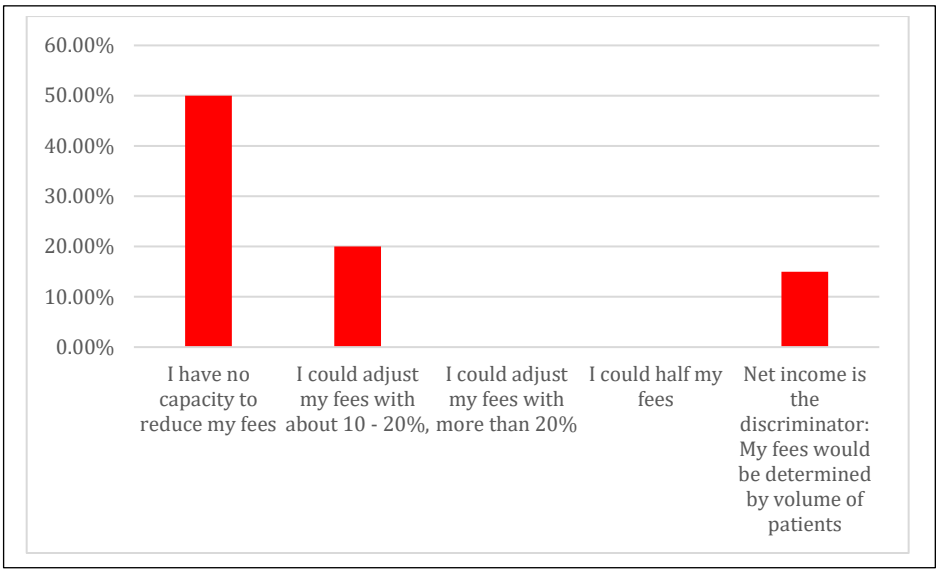
Health care services and providers

3.40. How (and how much) service providers will be paid is an issue that has not been addressed by the Bill. This is left wholly to the discretion of the NHIF and the Regulations that the Minister will make. There are no criteria, e.g. that the costs of medical practices must be considered, or the value of services, etc. A blanket power is handed to the Fund and the Minister. This has introduced significant uncertainty amongst healthcare professionals, including the members of SASCI.

3.41. The NHI Fund in section 41(1) will determine in consultation with the Minister of Health the "nature and mechanism" of provider payment. Section 20(3)(c) places the mandate of setting up a "unit of provider payment" in the hands of the CEO. In addition, the Benefits Pricing Committee will recommend the prices of benefits to the Fund. Section 41(3)(b), although not explicitly stating so, would require either employment of specialists by hospitals, or some joint payment mechanism, currently not possible under the Health Professions Act.

3.42. As stated above at par 1.9, SASCI is of the view that price setting mechanisms do not work, and prefers flexible negotiated models, whereby certain principles would be applied, so as to ensure both access, as well as the viability of practices.

3.43. It is argued by NHI officials that providers and suppliers would be able to reduce their prices on the basis of volume increases. SASCI tested this hypotheses with its members, as it is assumed that there is spare capacity, and/or a possibility to reduce fees from current fee levels (which

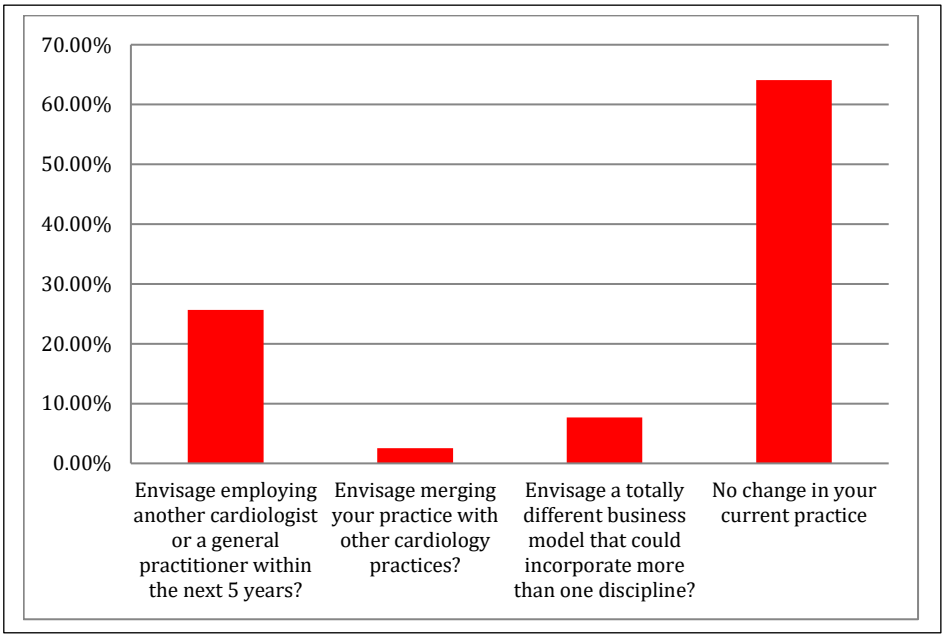


are, so the survey shows, set by 60% of respondents in line with medical scheme tariffs). The results are as set out below, with half the respondents stating they have no capacity to reduce their fees, close to 20% having some possibility to reduce 10 – 20%, and 15% of respondents indicating that if there is volume, it could affect pricing. Respondents however commented that in order for volume to pay a role, practices must be really large. Scepticism was also evident in replies as to whether the NHI Fund would be paying at all.

3.44. In terms of capacity, i.e. volume increases, SASCI established a baseline of how many hours the respondents were working per week. Close to 48% worked 60 or more hours a week, and another 50% working between 48 and 56 hours a week. When an ordinary work-week is taken at 48h, 75% of cardiologists work 56 or more hours a week, and 22,5% 48 hours. When asked whether they have spare capacity, just under 63%, unsurprisingly, stated they have none. 32,5% of respondents said they could work an additional 1 to 8 hours.

3.45. Another argument in relation to the possibility to effect price, and cost reductions in the NHI related to the possibility to re-configure the business structures within which specialists (and other professionals) currently practices. SASCI also tested this hypothesis, by asking practitioners whether they envisage changing their practice structures (in this one should consider that multi-disciplinary practices is prohibited, care co-ordination is still in its infancy

and the new category of "clinical associates" are not trained to render any specialist work. The results were as follows, with the majority of respondents not envisaging any change in their practice or business structure.



3.46. With the NHI being premised on such changes in the re-organisation of the private sector, as a precursor to contracting and payment, the lack of progress made in relation to engagement with this concept, as well as proposals as to how the "make this work", practically, is of concern. The only concrete proposals, also in terms of the necessary legislative changed. this far as come only from the HMI.

3.47. The bill makes provision for re-imbursement in accordance with "quality and value" of service provided in terms of section 10(1)(k). reference too is made in terms of section 41(3)(b) wherein payment is "performance" based. What exactly is meant with this, given that section 7(4) and 39(8) requires strict compliance with NHI Fund rules, is not clear. If providers are to be held accountable for the "performance, quality and value", which SASCI assumes refer to good patient outcomes, there should be freedom to act in the best interest of patients at all times. SASCI would not support any system that rewards religious adherence to rules, whilst not providing any flexibility and discretion to ensure that patient interests are served.

3.48. It is also not clear whether payments would be up front, or claimed, and what such claims process could entail. Reference is further made to "timeous" payments (section 19(1)(f)), but these time frames are not defined. SASCI proposes a set time of payment, in particular in view of the effects that non-payment, or late payment has had on service provision into the RAF and Compensation Fund.

Procurement

3.49. Section 38 of the NHI Bill creates the Office of Health Product Procurement in consultation with the Minister which will "coordinate" and "set parameters" for procurement. Clause 38(6)

provides however that the service provider and health establish (therefore not the NHI Fund) must procure. Product procurement is therefore seemingly centralized, as well as decentralised. This creates administrative problems and the office take long to address the needs of the patients particularly in emergency situations. The OHPP has a myriad of functions including coordination of procurement, distribution of health related products nationally, developing a national health product list among other things. Whereas centralized systems are exposed to possible corruption which could destroy the health care system, decentralised

3.50. In contrast to the reference to section 217 of the Constitution, the amendment proposed to the medicines pricing regime, states that the products must be sold "to the NHI Fund" (and therefore not to providers or establishments). The design of this system, coupled with statements relating to tenders (i.e. PFMA, *free pricing* on the basis of competition), *price-setting*, also for products and *price negotiations* are contradictory and confusing.

3.51. As stated above, for private practitioners and private establishment who already own or lease medical devices (in particular capital equipment), it would be impossible to adhere to the formulary or lists of the NHI in the utilisation of their preferred equipment, and it would be impossible to procure consumables and disposables from such lists if it does not fit the practice's equipment. The same principle would apply to private (and public!) hospitals where catheterisation laboratories are found.

3.52. The EML on which the NHI Formulary will be based is also outdated, and is not regularly updated, and circulated for comments by specialist organisations such as SASCI. This is probably as a result of the failure to enact regulations under section 90(1)(d) of the National Health Act on the essential drug (medicines) list. Our survey results show that most practitioners are not even aware whether their top five-prescribed medicines are included in the EML/EDL

3.53. The EEL, as stated above, is not in existence. And whereas there is a fairly long history of EMLs/EDLs, the EEL process and lists, a basic of which were released in 2011 but never implemented or formalised, is yet to be started. Unless completed, it would be impossible to bring section 39(4) into effect.

3.54. The requirement in section 38(6), that suppliers have to deliver directly to the health service provider and health establishments, would increase the product costs due to an inclusion of the logistical cost.

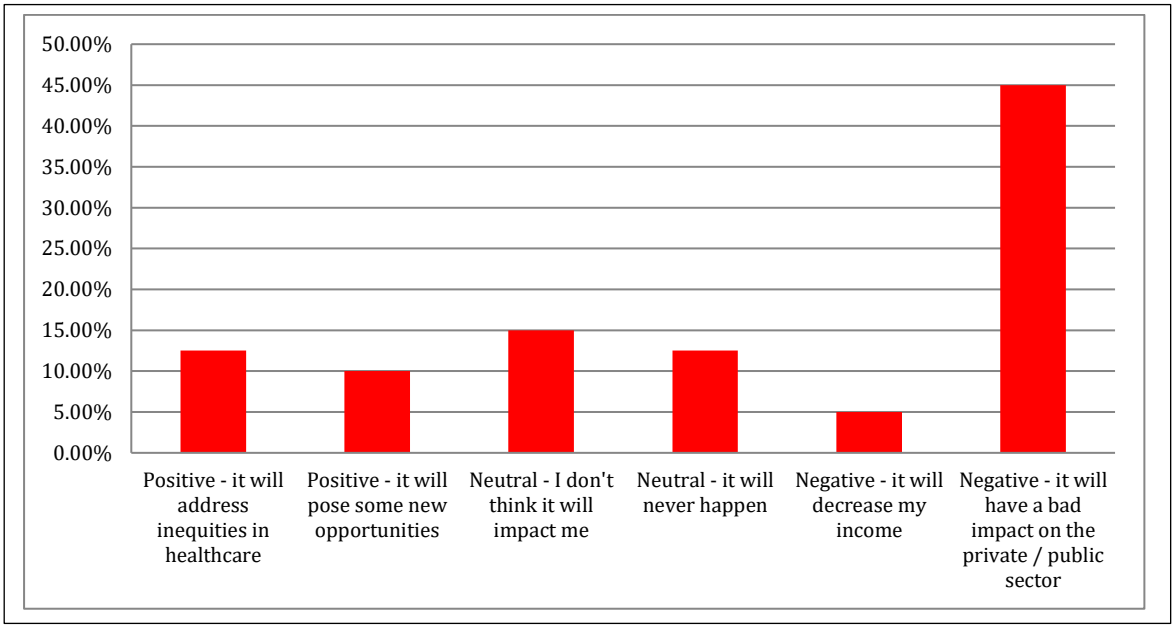
Role of medical schemes

3.55. Section 33 and section 6(o) of the Bill imply that Medical Schemes cannot fund NHI benefits, however, as pointed out above, could do so if a user for example skips the pathway referrals or deviates from treatment guidelines.

3.56. Access to healthcare and access to social security, as posited by section 27 of the Constitution include medical scheme cover, any limitation thereto would have to be reasonable and justifiable in terms of section 36 of the Constitution.

4. Conclusion

4.1 The extent to which there is skepticism in relation to the NHI is also evident from SASCI's survey (see graph below). This is, in all probability, due to the fact that true engagement on the Green and White Papers, as well as the Draft Bill, did not take place. Although there were



opportunities to make submission, and presentations (often without opportunities for questions or engagements on the basis of such answers) by officials, true there were no round-table consultations did not take place. The first consultation of this nature took place as part of the Presidential Health Summit in 2018, however, none of those aspects have found its way into the NHI Bill, or appear to have influenced the Bill.

4.2 In drawing conclusions and recommending the way forward it is important to take into account what the state of affairs is, currently where health care provision is concerned. There appears to be no "as is" analysis, nor any analysis of what the impact would be of, for example, different models of payment for specialists, or the types of re-organisation of specialist private practices.

4.3 The NHI Bill appears to pin its hope on volume increases, and structures that will, over time, produce benefit schedules, formularies and the likes. It also seems to delegate, without setting any principles according to which this delegation is to be exercised, the power to legislate to the Minister in regulations. As such, the Bill is not a true empowering law, and does not introduce any criteria that will allow it being measured against constitutional principles of "reasonableness", "progressiveness", "available resources" or the criteria of freedom, human dignity and equality, under section 36 of the Constitution.

4.4 SASCI is of the view that, given the flaws in the Bill, and the lack of proper consultation, the Bill is not ready to be passed by Parliament.

4.5 SASCI would also welcome the opportunity to make verbal submissions to the Portfolio Committee and to provide any additional information that could assist the Committee in its work.

4.6 SASCI can be contacted at;

Dr Hellmuth Weich (President SASCI) can be reached through the SASCI Executive Officer George Nel on 083 458 5954 and george@medsoc.co.za or sasci@sasci.co.za