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20 September 2018

BY EMAIL

ATTN: Dr Anban Pillay
Deputy Director – General
National Health Insurance
Email: anban.pillay@health.gov.za

Dear Dr Pillay,

Re: Comments on Draft National Health Insurance Bill (Gazette 41725 of 21 June 2018)

Genetic Alliance South Africa (GA-SA) is a non-profit, membership organisation uniting patient support groups, healthcare professionals and other stakeholders relevant to the care and prevention of congenital disorders (CDs), also known as birth defects. Based on collective membership of member groups, GA-SA represents almost 20 000 South Africans affected directly or indirectly by CDs, including rare diseases, inherited cancers and fetal alcohol syndrome.

CDs affect 1 in every 15 live births in South Africa[1] but are underreported via national surveillance by 98%[2] and as yet, are unprioritized as a health need in the country. Although the true contribution of CDs to the burden of disease is unknown due to the data deficit in South Africa – the proportion of deaths and disability due to CDs is known to increase in countries as they develop and transition epidemiologically. In developed countries, which completed this transition decades ago, CDs emerged and remain today as a leading cause of infant and child death – causing up to 28% of under-5 deaths[3]. Current lack of capacity in the community genetics sector in South Africa means that many of those affected remain undiagnosed or are misdiagnosed and the cause of death is incorrectly assigned. This prevents those affected, including the most vulnerable of our society (women, children and those living with disability) from having access to relevant, affordable health care. Early diagnosis and treatment can in some cases be lifesaving and minimize the impact of CDs on early childhood development, reducing the degree of disability and improve quality of life by up to 70%[4].

GA-SA applauds the Minister of Health for the release of the draft National Health Insurance Bill and welcomes this opportunity to submit comments relating to this draft. If the National Department of Health elects to hold further public hearings or briefing sessions on the draft Bill, GA-SA would welcome the opportunity to participate.

[1] Malherbe, H.L., A.L. Christianson, and C. Aldous, *Need for services for the care and prevention of congenital disorders in South Africa as the country's epidemiological transition evolves.* S Afr Med J, 2015. **105**(3): p. 186-188.
[2] Lebese, L., C. Aldous, and H. Malherbe, *South African congenital disorders data, 2006 - 2014.* S Afr Med J, 2016. **106**(10): p. 992-995.
[3] World Health Organization, *World Health Statistics 2015*. 2015, World Health Organization: Geneva. p. 164.
[4] Czeizel, A., Z. Intôdy, and B. Modell, *What proportion of congenital abnormalities can be prevented?* BMJ, 1993. **306**: p. 499-503.

COMMENTS/REPRESENTATIONS

1) Access to Healthcare

Chapter 2 of the Constitution of the Republic of South Africa - the Bill of Rights is the cornerstone of democracy in our nation. It enshrines the rights of all people in our country and affirms the democratic values of human dignity equality and freedom. It also states that the state must respect, protect, promote and fulfil the rights in the Bill of Rights. Equality includes the full and equal enjoyment of all rights and freedoms.

GA-SA is concerned that the draft Bill in its current form does not effectively provide for the constitutional rights of South Africans affected by a common or rare congenital disease – and instead, limits their rights to access healthcare.

Many CDs and more rare conditions are complex conditions involving a number of body systems requiring care from a variety of different medical specialists and allied healthcare professionals. While CDs are collectively common affecting one in every 15 live births, some conditions are extremely individually rare, affecting 1 in 2 000 live births or less. Specific implications in terms of the draft Bill include:

- **Section 10(2)(c)** - Adhering to referral pathways determined by a health establishment to have their condition funded is not always an option for those affected by CDs and rare diseases.
- **Section 10(3)(b)** - For many of the extremely rare conditions, there is no 'cost-effective' intervention in existence. Interventions for many CD and rare disease may be novel and expensive (often off-label use) and there is usually no alternative treatment. No provision is made in the draft Bill for conditions without a 'cost effective' solution. Rather, provision is made for a sub-set of the population i.e. those that have diseases that are common and for which there are available and affordable interventions. The draft Bill excludes those South Africans for which no such 'cost effective' interventions exist, for example those affected by rare metabolic disorders such as Lysosomal storage diseases which are treated via enzyme replacement therapy. This is an expensive, life saving therapy to which there is no alternative.
- **Section 10(6)** - The draft Bill makes provision that a user may purchase health care services not reimbursed by the fund through private healthcare insurance. However, the Medical Schemes Amendment Bill[5] published for comment on 21 June 2018, states that the Registrar may, after consultation with the Minister, restrict the extent of benefits offered by a medical scheme having regards to the benefits and services offered under the NHI Fund (Amendment to Section 34 of Act 131 of 1998).

The circumstances under which a persons rights may be limited as stated in Section 36(1) of the Constitution must be reasonable and justifiable in open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including — (a) the nature of the right; (b) the importance of the purpose of the limitation; (c) the nature and extent of the limitation; (d) the relation between the limitation and its purpose; and (e) less restrictive means to achieve the purpose.

These rights must be upheld through the draft Bill and access to care provided appropriately to all and not to the detriment of any requiring such healthcare.

2) FUND INCOME & COVERAGE

Section 3(b) of the draft Bill states that the Fund is the single public purchaser and financier of health services in the Republic of South Africa. However, there is no reference to the mechanism by which the fund will be financed and this needs to be clarified and detailed. A provisional funding framework should have been in place (i.e. a means to financially provide for the scheme) before the Bill was proposed. GA-SA's concern is the long-term viability of the NHI system since many pilot project sites already appear to be demonstrating financial problems. This has major implications for access to healthcare and the purpose for which the NHI Fund is created.

[5] Government Gazette Number 41726

One potential option under discussion for the financing of the NHI fund is via a tax levied for South African taxpayers to cover these costs. The sustainability of this approach is questionable for a nation where 10% of the population pay over 90% of taxes. In addition, many GA-SA member patient groups are committed to facilitating aid families where there is a rare disease patient, e.g. Rare Diseases South Africa. The huge financial burden imposed on these affected families due to the cost of caring for a family member with a CD or rare disease is already immense. In many cases, a parent or family member has to stop working to become a full-time carer, decreasing their earnings. Should these families also be required to fund the NHI Fund from a portion of their taxable earnings, this will further decrease the amount available to them to obtain appropriate complementary cover. Should this be the case, Section (4)(a) of the draft Bill, which outlines an objective of the fund to establish and maintain an efficient fund through the consolidation of revenue so as to protect users against financial risk – may well result in vulnerable groups having to pay for a mandatory service that does not provide for their needs and pay additional costs for private services – resulting in huge financial risk.

Section 5(C) of the draft Bill provides for the fund to "…*design healthcare services as advised by the relevant committee of the Board which will be purchased by the Fund on behalf of users"*. The question must be asked is how they will be considered to have services purchased that will actually cover the treatment of a less common condition. Also, how will they decide which conditions will be included? Patients affected by CDs and rare diseases will be required to contribute to the fund and register as a user but, as suggested by Section 5(C), will have no say in the purchase of services that will ultimately affect them. The NHI claims to prioritise services to those populations most in need and, by definition, this should include CDs and the rare disease community. From the current draft Bill it is unclear if these patients will be covered at all by the fund. Based on previously published NHI benefits framework, there is no provision made for coverage of the rarer disease patients. So, while these families will be required to register as users of the NHI fund, many will not have the treatment of their conditions funded.

GA-SA also raises the issue of 'cost effectiveness' relative to personal risk/cost and the overall socioeconomic impact which do not appear to have been considered. For example: conservative treatment of specific scoliosis patients (where the curve may be treated) involves physiotherapy and bracing (R40 000 per brace) versus spinal surgery (R200-300 000). Such major surgery should be the last resort, and only after the child has stopped growing – what is currently taking place in State since bracing is currently not available is that surgery is offered in all severe cases (even those that bracing would negate surgery) and at an early age, resulting in stunting. Many children remain undiagnosed resulting in repeated visits to healthcare facilities requiring time off school and work for their parents, transport costs and ultimately a reduced contribution to the workforce and economy.

Further general comments related to the financing of the fund:

- We are concerned about the reported fact that 85% of public hospitals and clinics could not be accredited to participate in an NHI system because they were unable to comply adequately with basic healthcare norms and standards, such as maintaining proper hygiene and having medicines available. To be overcome, these problems require significantly improved operational and financial management.
- For South African citizens to truly benefit from a universal health coverage system there will be a need for stronger accountability for wrongdoing and accountability amongst political and civil servants involved in the operation of the fund. Failure to do this will directly impact the entitled user/beneficiary's *right to life and to have access to health care services*. Furthermore, t*he state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.*

3) CONTINUATION OF CARE & REFERRAL PATHWAYS

Section 10(2)(c) makes provision that a user must comply with referral pathways determined by a health establishment, failing which, the fund will not be liable to make payment of any service benefits. In the case of a less common CD, this is not viable.

While the draft Bill addresses the phases by which the proposed NHI will be implemented it fails to deal with the practical issue of continuation of care by existing treating healthcare practitioner during this phase. Patients already diagnosed with a CD (common or rare) prior to the implementation of NHI and the draft Bill may have already been receiving much needed treatment under the care of a specific sub-specialist or multidisciplinary team of specialists and allied health care professionals. A delay in receiving continued lifesaving care could prove fatal.

Often these practitioners are consulted by the patient due to the practitioners' specialty and expertise in treating a particular problem and not due to geographic convenience. With such a shortage of medical specialists in the country, geographical convenience is often a luxury many CD and rare disease patients do not have, particularly those outside of major urban areas boasting an academic facility where most such specialists are located.

In addition, the requirement specified in the draft Bill that patients adhere to referral pathways determined by a health establishment, which may commence with a patient being assessed by a nurse or other primary health care provider is a likely waste of time and resources in the case of CD and rare disease patients. While this may be an appropriate referral pathway for someone affected by a less severe and more common illness e.g. a common cold, the same standard of referral cannot be applied to all. The previous diagnosis and the treatment already received or ongoing by the patient must be taken into consideration to ensure the most effective, timeous access and reimbursement for certain conditions.

Our Patient's Rights Charter makes provision for *the right to choose a particular health care provider for services or a particular health facility for treatment, provided that such choice shall not be contrary to the ethical standards applicable to such health care provider or facility* and *not to be abandoned by a health care professional who or a health facility which initially took responsibility for one's health without appropriate referral or hand-over.*

Further the delays in accessing the appropriate treatment for a rare disease sufferer can have dire consequences and may even result in death. Provision is made in Section 11(2)(b) that a user of the Fund may only seek the services of a specialist without a referral from his or her healthcare provider in cases of an emergency.

GA-SA requests clarity in the draft Bill on the definition of emergency services and a clear definition of the process by which patients and healthcare practitioners of rare or specialised conditions, including CDs, are integrated into NHI healthcare services.

4) RIGHTS OF FUND USERS/PATIENTS:

4.1. Right to Informed Consent

The right to informed consent places responsibilities on the individual patient according to the Patient's Right Charter:

- *To take care of his or her own health;*
- *To utilise the health care system properly and not to abuse it;*
- *To know his or her local health services and what they offer;*
- *To provide health care providers with relevant and accurate information for diagnostic, treatment, rehabilitation or counselling purposes;*

- *To advise health care providers of his or her wishes with regard to his or her death;*
- *To comply with the prescribed treatment or rehabilitation procedures;*
- *To enquire about the related costs of treatment and/or rehabilitation and to arrange for payment; and*
- *To take care of the health records in his or her possession.*

To enable patients to uphold their right and excise their responsibilities they must have access to their health records. The draft Bill states that a user is entitled - *"to access to any information or records relating to his or her health in the custody of the Fund, in line with the provisions of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000), in order to exercise or protect his or her rights"*

We consider the process defined in the Promotion of Access to Information Act (PAIA), 2000 (Act No. 2 of 2000) (PAIA), too onerous for an individual and lacks the efficiency and speed by which a user/beneficiary may require such information. By linking the right to access health records to the PAIA, the draft Bill places undue burden on the individual to exercise both, their rights and responsibilities in this regard.

This undue burden will further impact the right of the patient to be given full and accurate information about the nature of one's illnesses, diagnostic procedures, the proposed treatment and risks associated therewith and the costs involved; and obtain a second opinion to a health provider of one's choice.

4.2. Rights relating to personal information

The PAIA defines *'personal information'* as *information about an identifiable individual, including, but not limited to*

(a) information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the individual;

(b) information relating to the education or the medical, criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved; (c) any identifying number, symbol or other particular assigned to the individual;

(d) the address, fingerprints or blood type of the individual;

(e) the personal opinions, views or preferences of the individual, except where they are about another individual or about a proposal for a grant, an award or a prize to be made to another individual;

(f) correspondence sent by the individual that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence;

(g) the views or opinions of another individual about the individual;

(h) the views or opinions of another individual about a proposal for a grant, an award or a prize to be made to the individual, but excluding the name of the other individual where it appears with the views or opinions of the other individual; and

(i) the name of the individual where it appears with other personal information relating to the individual or where the disclosure of the name itself would reveal information about the individual,

but excludes information about an individual who has been dead for more than 20 years;

In Section 5(C) the draft Bill states:

"Without derogating from any other right or entitlement incurred under this Act or under any other law, and subject to affordability and within the means of the Republic of South Africa, a user is entitled - …"

"…to the protection of his or her rights to privacy and confidentiality in that he or she must grant written permission for the disclosure of personal information in the possession of or accessible to the Fund, unless the information -

(i) is shared amongst health care providers for the lawful purpose of serving the interests of users;

(ii) is required by accredited health care providers or suppliers or researchers for the lawful purpose of improving health care practices and policy; or

(iii) is utilised by the Fund for any other lawful purpose related to the efficient and effective functioning of the Fund…"

This provision is vague, lacks legal validity and will not withstand constitutional challenge as no law may limit any right entrenched in the Bill of Rights as defined in our Constitution. As currently drafted it means the patient is entitled to the benefits which they would ordinarily be entitled to under the Medical Schemes Act 131 of 1998 and the fund should not seek to replace these available. There is no alignment between the proposed section in the draft Bill and the Medical Schemes Amendment Bill.

4.3. PATIENT AND/OR CIVIL SOCIETY REPRESENTATION IN FUND PROCESSES AND COMMITTEES

The draft Bill excludes representation from either health related non-governmental organisations (NGOs), civil society or consumers in both the Benefits Advisory Committee and Health Benefits Pricing Committee.

It furthermore makes no provision for public and /or civil society representation, or public comment, in "*the design of the health care service benefits and goods"* and *"health care referral networks of users".* It is assumed that this will include which conditions are included/covered by the benefits and services.

It is our position that member representation of each of these groups must be included in these committees and process. Should they not be included, then any decisions made by the committee must be after public consultation, which should be within a formal process.

4.4. Accountability for Access to Healthcare

The draft Bill state that "*The Fund must, in consultation with the Minister, purchase comprehensive health service benefits on behalf of…",* while the Constitution makes the Minister of Health (the Minister), as representative of the executive accountable for access to healthcare for our citizens.

Our concern is that in the case where access to services or health technology occurs the dual accountability would lead to a situation where a patient is caught between the fund and the Minister.

In addition to the above, those protected by our Constitution do have the right to complain about health care services, to have such complaints investigated and to receive a full response on such investigation. In this instance the situation of the dual accountability created by the draft Bill will further complicate the complaint process as that defined currently in the draft Bill in relation to the fund.

5) COST COVERAGE

As set out in Section 12(1), the draft Bill indicates that the fund will only pay for health services for a condition that are purchased on the users behalf by the fund from certified and accredited service providers at no cost. Our concern with this provision as a CD community and rare disease community is that numerous common and rare CDs affect many body systems and as a result are treated simultaneously by a range of specialists – a multidisciplinary team of specialists and allied health care professionals.

More than 80% of CDs are genetic or partially genetic in their aetiology. Serious CDs and rare diseases are life limiting or chronically debilitating diseases often resulting in lifelong disability. They vary in birth prevalence from the more common disorders such as Down syndrome to those of such low prevalence (one in less than 2 000) that special combined efforts are needed to address them. While the contribution of CDs and rare diseases (which are individually rare but collectively common) are proportionally increasing in importance as mortality and morbidity from infectious diseases is decreasing – this is not being perceived as a health need due to the lack of empiric data in South Africa. As for many low and middle income countries, we lack the observed data via surveillance to provide the evidence base. This results in an underestimate of the true contribution of CDs to the burden of disease, these issues continue to remain unprioritized as healthcare issues, services remain neglected and patients remain undiagnosed and misdiagnosed. Tackling CDs and prioritising this growing health need is likely the only way that child mortality will be significantly reduced in the next 20 years. More importantly – there is a cost to not providing care for those affected and our acknowledgement and investment in these patients can make significant changes to their quality of life.

GA-SA is concerned that certain areas of specialty that are needed to treat CDs and rare diseases may not be funded by the NHI Fund or further may be in locations which cannot reasonably accessed by affected patients. Currently in South Africa, the 12 practising medical geneticists in the country are located in only three of the nine provinces, and the eight genetic counsellors in the state sector are in only two of the nine provinces[6]. If there is no relevant specialist in Province to diagnose a patient, how can the relevant treatment even be known let alone made available and accessed? How will this capacity, and supporting genetic testing through laboratories (i.e. NHLS) be increased and relevant geographical coverage be ensured so that services can be provided countrywide and universally to all?

6) DEFINITIONS

The following terms are used ambiguously in the draft Bill and need to be clearly defined in the context of their use in the draft Bill:

Page 6:

- Mandatory prepayment
- Active purchasing
- Undesirable, unethical

Page 7:

- Progressive realization
- Good quality personal health care services
- Universality and social solidarity

Page 13:

- Health establishment and health agency
- Beneficiary
- Page 17
- financial risk (according the definition in the Medical Schemes Act)
- Page 19
- Portablity (in this context)

[6] Malherbe, H., et al., *The contribution of congenital disorders to child mortality in South Africa*, in *South African Health Review 2016*, A. Padarath, et al., Editors. 2016, Health Systems Trust: Durban. p. 137-152.

Page 22:

- Quality health service benefits (for a rare disease patient this may mean novel, expensive therapies)
- Unreasonable grounds

Page 24

- Cost-effective (in this context)
- Adequate notice
- Reasonable opportunity

Page 27:

- Complementary health service benefits

Page 29:

- Comprehensive

GA-SA and the patients and healthcare providers represented through its membership do not believe that the draft Bill can be accepted in its current format.

We request that these comments are addressed and shortcomings rectified through further consultation with the various stakeholders and groups. True universal health coverage is where citizens can access health services without incurring financial hardship: a system of protection which provides the equality of opportunity for people to enjoy an attainable level of health. Such a healthcare service should be available to ALL registered users, and include promotive, preventative, curative, rehabilitative and palliative health services, regardless of socio-economic or health status of those persons at no cost impact to the registered user.

All South Africans affected by common and rare congenital disorders are entitled to access appropriate, timely care and efforts must be undertaken to ensure this especially vulnerable group are not excluded and left behind within the context of NHI.

Yours sincerely,

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