

Comments on PMB review consultation document Third draft

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Introduction

The BHF wishes to express its disappointment at the manner in which the Prescribed Minimum Benefits have been reviewed and the apparent lack of regard for the constitutional and other legal principles involved. This submission is to be read in conjunction with BHF's response to Draft 2 dated 12th September 2008.

We reiterate that the skewing of the PMBs towards catastrophic cover is not in keeping with the constitutional requirement of access to health care services. It does not support the concept of equity of access and undermines the basic principle of health service delivery that prevention is better than cure. The cost of a health intervention should not be the only determinant of whether or not it is a prescribed minimum benefit but it seems that this is the basis upon which the PMB package has been reviewed.

Medical schemes are not insurance companies. The catastrophic cover approach is one that has been endorsed for centuries in the insurance environment and still is. There is a role for insurance against catastrophic cover. It should not therefore be the sole and primary focus of medical scheme cover. BHF believes that medical schemes should be vehicles for access to health care for everyone. This has always been the primary reason for medical schemes' existence – not to 'insure' a small portion of the membership in the unlikely event of major health catastrophes but to assure access to routine health care services necessary to maintain the health status of their members thereby precluding in many instances the possibility of a catastrophic condition ever arising.

BHF also has a problem with the fact that its submissions in this regard appear to have been largely ignored by the Department of Health. This is despite the fact that the BHF is the only representative organisation for medical schemes in South Africa and that the majority of medical schemes are members of BHF.

BHF has repeatedly submitted that the thinking that previously informed the structuring of the PMBs is no longer apposite. The fear of 'dumping' high cost

patients that are members of medical schemes into the public sector is unconstitutional and self defeating. The State is ultimately liable for ensuring access to health care services – it cannot escape this constitutional principle. People who cannot afford medical aid cover for expensive catastrophe oriented PMBs will simply drop out of the medical scheme system and become a burden on the state anyway. However, if they could remain as members of medical schemes offering a balanced range of Prescribed Minimum Benefits, they would be contributing to a risk pool that is all the larger for their presence there, obtaining their own much needed health care which might in many cases preclude the likelihood of a catastrophic condition, and the state would be relieved from the pressure of meeting their every health care need, catastrophic or otherwise.

As the PMBs stand currently, the likelihood is that these people will become a burden on the state not only for catastrophic cover but also for their everyday health needs because they cannot afford to be members of a medical scheme. Medical schemes would like to increase their membership numbers not decrease them. The present PMB package renders this impossible as it is too expensive. One of the fundamental constitutional concerns around the current PMB package is that they effectively deny access to care for a great many people including members of medical schemes. Those fortunate enough to be members must in some cases wait until they are catastrophically ill before they can have access to the necessary health care.

In the current draft of the PMBs the following are subject to mandatory cover only as far as surgical management is concerned –

- Spina bifida – it is iniquitous to be obliged to treat this condition surgically only to be able refuse payment for medical management because medical management of the condition is not a PMB. “Spina bifida results from failure of fusion of the caudal neural tube, and is one of the most common malformations of human structure. The causes of this disorder are heterogeneous and include chromosome abnormalities, single gene disorders, and teratogenic exposures. However, the cause is

not known in most cases. Up to 70% of spina bifida cases can be prevented by maternal, periconceptional folic acid supplementation. The mechanism underlying this protective effect is unknown, but it is likely to include genes that regulate folate transport and metabolism. Individuals with spina bifida need both surgical and medical management. Although surgical closure of the malformation is generally done in the neonatal period, a randomised clinical trial to assess in utero closure of spina bifida has been initiated in the USA. Medical management is a lifelong necessity for individuals with spina bifida, and should be provided by a multidisciplinary team." i

We submit that medical scheme benefits should not favour a small wealthy elite but that they should be a vehicle for access to health care services for everyone who can afford to contribute something towards their own healthcare. Many people at the moment finance their own health care needs by way of out of pocket payments because they cannot afford membership of a medical scheme.

Legal Principles that Should Inform the PMB Review

There are a number of legal issues concerning the PMBs which must be considered when they are reviewed as required by the Explanatory Note in the Regulations. The latter states that a review shall be conducted at least every two years by the Department [of Health] that will involve the Council for Medical Schemes, stakeholders, Provincial health departments and consumer representatives. In addition, the review will focus specifically on development of protocols for the medical management of HIV/AIDS.

These reviews shall provide recommendations for the revision of the Regulations and Annexure A on the basis of:

(i) inconsistencies or flaws in the current regulations;

- (ii) the cost-effectiveness of health technologies or interventions;
- (iii) consistency with developments in health policy; and
- (iv) the impact on medical scheme viability and its affordability to members.

We submit that thus far none of these four principles have demonstrably been taken into account in the current PMB review. This is problematic from a legal perspective since the outcome of the review could be challenged on the basis of the abovementioned regulatory provisions.

The principle behind the right to have access to healthcare services is not the right to receive treatment for a specific diagnosis. The focus of the right is not on health care services following from a particular diagnosis but on health care services in general. The scope of the right is very broad as is demonstrated by the express inclusion of the right to reproductive health care services in the Constitution. The current PMB structure is based as much on severity as it is on diagnosis. Many of the conditions in the PMB list only become classified as PMBs when they reach a certain level of severity. In some cases if the conditions that are the underlying cause or aggravating factor are treated initially the "diagnosis" reflected in the PMBs will not arise.

The chronic conditions are not prescribed minimum benefit conditions by virtue of regulation 7 of the Regulations to the Medical Schemes Act which defines a 'prescribed minimum benefit condition' as a condition contemplated in the Diagnosis and Treatment Pairs listed in Annexure A or any emergency medical condition. The chronic diseases are not listed in the Diagnosis and Treatment Pairs format. Moreover the diseases of diabetes, glaucoma, cardiac failure, asthma, epilepsy, systemic lupus erythematosus, chronic obstructive pulmonary disorder and ulcerative colitis are all covered directly or indirectly within the DTPs. It is therefore not clear what the status of the list of chronic conditions is except that they do not form part of the Prescribed Minimum Benefits.

The PMB package is neither clear or nor certain in many instances for a number of different reasons. One of these is frequent overlapping of the various diagnosis treatment pairs at various levels.

Some examples are -

Code: 213A

Diagnosis: Difficulty in breathing, eating, swallowing, bowel or bladder control due to non-progressive (including spinal) neurological condition or injury.

Other codes that overlap with 213A are:

Code: 906A

Diagnosis: Acute generalized paralysis, including polio and Guillain-Barre

Code: 341A

Diagnosis: Basal ganglia, extra-pyramidal disorders; other dystonias NOS

Acute generalized paralysis and basal ganglia, extra-pyramidal disorders can both have the effects or symptoms reflected in the diagnosis in 213A. The difficulty in eating referred to in 213A could be mechanical, i.e., inability to hold a spoon with food in it and direct it to one's mouth because of an inability to co-ordinate movements of the muscle involved or anatomical i.e. the inability to chew or swallow due to paralysis. The point is that the diagnosis in Code 213A is not in fact a diagnosis. It is a list of symptoms that fit many diagnoses some of which appear in Codes 906A and 341A. In terms of the rules of legislative interpretation the specific case excludes the general. However medical practitioners not knowing this may be confused as to which code to use with regard for instance to a patient who has an extrapyramidal disorder that is causing difficulty eating because the patient cannot feed himself. Despite this the abovementioned has been retained apparently without question in the latest draft of the PMBs. We stress that this is just one example. Another example of inconsistency is -

CODE: 394B

DIAGNOSIS: Angle-closure glaucoma

Treatment: Iridectomy; Laser surgery; medical and surgical management

CODE: 405B

DIAGNOSIS: Glaucoma associated with disorders of the lens

Treatment: Surgical management

The optic nerve is made up of many nerve fibers that carry images to the brain. It's like an electric cable containing numerous wires. When glaucoma damages the optic nerve fibers, blind spots develop. If the entire nerve is destroyed, blindness results. Chronic open-angle glaucoma is the most common form of glaucoma. Typically, open angle glaucoma has no symptoms in its early stages, and vision remains normal. As the optic nerve becomes more damaged, blank spots begin to appear in the field of vision. If all the optic nerve fibers die, blindness results. Some people are born with the iris (the colored part of the eye) too close to the drainage angle. In these eyes, which are often small and farsighted, the iris can be sucked into the drainage angle and block it completely. Since the fluid cannot exit the eye, pressure inside the eye builds rapidly and causes an acute closed-angle attack.

Symptoms of closed-angle glaucoma may include:

- blurry vision;
- severe eye pain;
- headache;
- rainbow-colored halos around lights;
- nausea and vomiting.

This is a true eye emergency. Unless this type of glaucoma is treated quickly, blindness can result. Unfortunately, two-thirds of those with closed-angle

glaucoma develop it slowly without any symptoms warning an acute attack might be coming. Treatment can prevent vision loss, but as a rule damage caused by glaucoma is irreversible.

Eyedrops, laser surgery, and conventional surgery can help prevent further damage. In some cases, oral medications may also be prescribed. Glaucoma is usually controlled with eyedrops taken daily. These medications lower eye pressure, either by decreasing the amount of fluid produced within the eye or by improving the flow through the drainage angle.

With any type of glaucoma, periodic examinations are very important to prevent vision loss. Because glaucoma can progress without the patient noticing, changes in treatment may be necessary from time to time.

Even if a glaucoma patient's eye pressure remains low overall, fluctuations in eye pressure may still be associated with a shrinking peripheral field of vision, South Korean researchers say.

Researchers at the Yonsei University College of Medicine in Seoul studied 408 eyes of patients (average age 66.5 years) who'd had triple glaucoma treatment, including surgery. All the patients had low intraocular pressure (IOP) after surgery. The patients, whose visual field and IOP were checked for a number of years after surgery, were divided into two groups those with greater IOP fluctuation and those with less fluctuation.

When the final follow-up examination was conducted 13 years after surgery, patients with greater IOP fluctuation had significantly worse visual field loss. The study was published in the August issue of Archives of Ophthalmology.

In recent years, it has been shown that at least one-third of glaucoma patients have eye pressures in the "normal range", which is 10 to 21mm Hg. This information has challenged traditional thought that glaucoma is a disorder of high eye pressure. There are consequently multiple theories regarding the cause of glaucoma.

Primary Open Angle Glaucoma

Primary open angle glaucoma (POAG) is the most common of all types of glaucoma. The condition is diagnosed in the presence of an open angle, evidence of optic nerve damage, and peripheral vision loss consistent with glaucoma on a visual field test. Patients are usually treated with eye-drop and/or oral medications first, reserving laser and surgical procedures for "maximum medical therapy" failures, i.e., patients who have progression of glaucoma with a medical regimen. If eye-drop medication is chosen as the initial treatment, many ophthalmologists will recommend treatment of just one eye first, utilizing the second eye as a control, or "barometer", by which to gauge the effect of treatment. Patients who have progression of glaucoma despite medical therapy and, perhaps, argon laser trabeculoplasty (ALT, or laser treatment) are usually recommended to have a glaucoma filtration procedure (trabeculectomy). Certain patients who have failed an initial glaucoma filtration procedure may be recommended for implantation of a glaucoma drainage device.

Normal pressure glaucoma, also known as low-tension glaucoma, occurs in approximately one-third of all patients afflicted with glaucoma. Patients with this condition have essentially the same findings as patients with primary open angle glaucoma (abnormal optic nerve findings and visual field loss), except that they are not demonstrated to have high intraocular pressures.

Normal pressure glaucoma is often treated with eye-drop medications in attempt to further reduce pressure and stabilize the visual field. Glaucoma refers to a group of disorders that lead to damage to the optic nerve, the nerve that carries visual information from the eye to the brain. Damage to the optic nerve causes vision loss, which may progress to blindness. Most people with glaucoma have increased fluid pressure in the eye, a condition known as increased intraocular pressure.

There are four major types of glaucoma:

- Open angle (chronic) glaucoma
- Angle closure (acute) glaucoma

- Congenital glaucoma
- Secondary glaucoma

Open angle (chronic) glaucoma is by far the most common type of glaucoma. In open angle glaucoma, the channels in the angle gradually narrow with time, making it hard for the fluid to drain properly. The buildup of fluid causes increased pressure in the eye. This increased pressure pushes on the junction of the optic nerve and the retina at the back of the eye, reducing the blood supply to the optic nerve. Open angle glaucoma tends to run in families. The risk is higher if the patient has a parent or grandparent with open angle glaucoma. People of African descent are at particularly high risk for this disease.

Secondary glaucoma is caused by other diseases, including eye diseases such as uveitis, systemic diseases, and drugs such as corticosteroids. Congenital glaucoma, which is present at birth, is the result of abnormal development of the fluid outflow channels of the eye. Surgery is required for correction. Congenital glaucoma is often hereditary.

In view of the above one must ask the following questions:

1. Why does the PMB exclude glaucoma that is not associated with a disorder of the lens and that is not angle closure glaucoma?
2. Why is glaucoma only covered under the PMBs when surgical management is necessary? Note that the chronic conditions list, although it covers medical management of glaucoma, is not technically a part of the PMB regulations for reasons that are explained elsewhere.
3. Why is it that when medical management with the use of drops etc is appropriate then glaucoma other than angle closure glaucoma is not a PMB?
4. Why is it that post-operative care for non angle closure glaucoma, involving the use of medication to control intra-ocular pressure is not a

PMB when such postoperative management is clearly important to avoid a recurrence of the condition?

5. Is congenital glaucoma that is not angle closure glaucoma a prescribed minimum benefit condition or not? If not, why not? Why is there a difference between glaucoma associated with disorders of the lens and congenital glaucoma that is not associated with disorders of the lens when the end result of both is blindness?
6. Is open angle glaucoma a prescribed minimum benefit condition or not? Does it only become a prescribed minimum benefit condition when surgery is indicated?
7. If people of African descent are at a higher risk for this condition than other groupings within the population is it not unfairly discriminatory that only surgical management of open angle glaucoma is a prescribed minimum benefit?
8. Why is secondary glaucoma not a prescribed minimum benefit condition? If it is a PMB condition when is it a PMB condition – only when surgery is required?
9. Is low tension glaucoma a PMB condition or is it included in the reference to primary or open angle glaucoma referred to in Code 407B (see below)? It is apparently different to open angle glaucoma in that there is normal intraocular pressure.
10. Code 407B refers to “primary and open angle glaucoma” does this mean the same as “primary open angle glaucoma” or is it intended to refer to primary glaucoma and open angle glaucoma?

The need for these questions is only emphasised by a third code involving glaucoma within the PMB which reads as follows-

CODE:407B DIAGNOSIS: Primary and open angle glaucoma with failed medical management.

Treatment: Trabeculectomy; other surgery.

It is clear from the above sample analysis that the PMBs have not been created from any significant background medical knowledge. There is no clinical logic behind the PMB package and no health science. It is purely a financial risk management tool for keeping high cost cases out of state health establishments. As such it is unconstitutional.

The inappropriate focus on surgical interventions as opposed to nonsurgical interventions within the Prescribed Minimum Benefits package is due to the fact that the focus of the PMB is on costs of treatment and not on access to health care, health outcomes or the efficient and effective management of health conditions in their initial stages. At its most extreme, the PMB package encourages that which it seeks to avoid because if people do not have the means to access health care services early then cases become prescribed minimum benefit conditions when this could have been avoided. The object of medical management of glaucoma is to prevent blindness and avoid surgery. If such medical management is not accessible to a patient due to lack of funding, then not only surgery becomes an increased likelihood but so does blindness.

Another reason for internal inconsistency and interpretational difficulties within the PMB is that there is conflation of diagnosis and symptoms throughout. For example Code :125D DIAGNOSIS: Adult respiratory distress syndrome...coincides with Code 213A – difficulty breathing. It is much easier for a clinician to observe “difficulty breathing” than to pronounce that the patient is suffering from ARDS.

BHF has endeavoured to point out such inconsistencies – of which there are many – to no avail. There is no evidence in the latest draft of the PMBs that there is any intention to remedy the inconsistencies. This could lead to a legal inference that the PMBs are unreasonable. Regulations that are unreasonable are open to legal challenges. In *Minister of Health and Another NO V New Clicks South Africa (Pty) Ltd and Others (Treatment Action Campaign and Another as Amici Curiae)*ⁱⁱ, the Constitutional Court stated that under section 33

of the Constitution, administrative decisions can now be reviewed for reasonableness. The court also said that there is nothing to suggest that the interim Constitution, or the Constitution which took its place, intended to exclude delegated legislation from what had previously been understood as being administrative action. On the contrary, it said, the Constitution points in the opposite direction. Yacoob J in *Government of the Republic of South Africa and Others v Grootboom and Others*ⁱⁱⁱ said:

"The State is obliged to act to achieve the intended result, and the legislative measures will invariably have to be supported by appropriate, well-directed policies and programmes implemented by the Executive. These policies and programmes must be reasonable both in their conception and their implementation. The formulation of a programme is only the first stage in meeting the State's obligation. The programme must also be reasonably implemented. An otherwise reasonable program that is not implemented reasonably will not constitute compliance with the State's obligations." (our italics).

Sachs J has stated with regard to reasonableness that –

"The standard of reasonableness is used as a measure throughout the Constitution, notably in regard to the fulfilment of positive obligations to realise social and economic rights, and with respect to permissible limitations of protected rights. I see no reason why the standard should not be used as the overall principle for measuring whether or not subordinate legislation fits appropriately with the scheme of its empowering law. Reasonableness is capable of being determined objectively...Proportionality will always be a significant element of reasonableness. What the concept of proportionality loses in terms of predictability, it more than makes up for by being congruent with context and responsive to the intensity with which the relevant constitutional values are triggered."^{iv}

It is submitted that both the current PMBs and the reviewed version is unconstitutional because –

1. Unreasonably, they do not take into account the interests of the individual needing healthcare. They only take into account the interests of the state in avoiding certain high cost interventions. The PMBs are currently about risk management on behalf of the state and not access to health care services by citizens and permanent residents. For example only surgical management of spina bifida – a very serious condition that requires both medical and surgical management – falls under the PMBs.
2. Unreasonably, they ignore the demographics of the South African population as a whole or the incidence of certain health conditions within the medical scheme membership – they simply look at the cost of an intervention no matter how unlikely or rare the condition may be.
3. They do not take account of the Constitutional mandate to the state to progressively achieve the realization of the right of access to health care services because of their preoccupation with minimizing financial risks to the state. The current draft of the PMBs forces the vast majority of people to pay for cover that many of them are not likely to need in their lifetimes in order to ensure that the few who will need it are not a burden to the state coffers when the time comes. This does not support the constitutional principle of equality before the law neither does it acknowledge the right of access to health care services of the majority of medical scheme beneficiaries.
4. The PMBs do not satisfy the requirement of legal certainty. For instance, what exactly are these “other disorders of the stomach and duodenum” when the following are also expressed as PMBs?

Cancer of the gastro-intestinal tract, including oesophagus, stomach, bowel, rectum anus – treatable: medical and surgical management which includes chemotherapy and radiation therapy;

Gastric or intestinal ulcers with haemorrhage or perforation: medical management; endoscopic diagnosis; medical management.

Gastroenteritis and colitis with life threatening haemorrhage or dehydration regardless of cause: medical management.

What happens where there is no haemorrhage or perforation of the ulcer but this had to be discovered endoscopically – is the endoscopy covered under PMBs or not? When the cancer becomes untreatable is it no longer covered under PMBs? Exactly when is it 'untreatable'? When it is just about cured? When it is incurable or not severe enough? What happens if there is gastroenteritis but no colitis?

What is the rationale behind "uncomplicated hernias under age 18"? Why are people over the age of 18 with uncomplicated hernias not entitled to the same treatment? The word lawyers use for this kind of provision is "arbitrary". Another phrase that springs to mind is "unfairly discriminatory". "Arbitrary" is undesirable because it is contrary to the constitutional right of equality before the law and therefore open to legal challenge.

In *Van Der Merwe v Road Accident Fund and Another (Women's Legal Centre Trust As Amicus Curiae)*^v the court observed –

"For the appropriate test I turn to *Prinsloo v Van der Linde and Another*^{vi} in which this Court explained that in the first leg of the equality test the constitutional State is bound to act in a rational manner:

'It should not regulate in an arbitrary manner or manifest "naked preferences" that serve no legitimate governmental purpose, for that would be inconsistent with the rule of law and the fundamental premises of the constitutional State. The purpose of this aspect of equality is, therefore, to ensure that the State is bound to function in a rational manner. This has been said to promote the need for governmental action to relate to a defensible vision of the public good, as well as to enhance the coherence and integrity of legislation.'

It is so that laws rarely prescribe the same treatment for everyone. Yet it bears repetition that when a law elects to make differentiation between people or classes of people it will fall foul of the constitutional standard of equality if it is shown that the differentiation does not have a legitimate purpose or a rational relationship to the purpose advanced to validate it. Absent the pre-condition of a rational connection the impugned law infringes, at the outset, the right to equal protection and benefit of the law under s 9(1) of the Constitution. This is so because the legislative scheme confers benefits or imposes burdens unevenly and without a rational criterion or basis. That would be an arbitrary differentiation which neither promotes public good nor advances a legitimate public object. In this sense, the impugned law would be inconsistent with the equality norm that the Constitution imposes, inasmuch as it breaches the 'rational differentiation' standard set by s 9(1) thereof."

5. The PMB review seeks to preserve the status quo as far as the underlying approach to PMBs is concerned. The constitutional court has said that -
"The maintenance of 'business as usual' is not a constitutional principle, and the concept of reasonableness should not be used as an apparently neutral instrument which, regarding the status quo as the settled norm, serves to block transformation and freeze challengeable aspects of our public life"vii.

The policy environment of the PMBs has changed significantly since the year 2000. Medical schemes are no longer allowed to risk rate, they have to charge the same contributions irrespective of age, health status etc. If medical schemes become unaffordable to the general public, and it could be said that they already are, then they will no longer even be able to serve the purpose of treating the majority of high cost cases in the private health sector as was the original intention. Medical schemes do not 'dump' patients onto the public health sector. Patients who can only afford limited cover with a medical scheme have a constitutional right to obtain the health care they cannot afford from the State. The State has the primary

obligation to ensure the progressive realization of the right of access to health care. Medical schemes are simply a State created vehicle for promoting access to health care services. There is no sense in expanding their liabilities to the point where they are no longer effective in securing access to health care services for their members. They do not have the resources of the State at their disposal and are restrictively regulated in terms of the contributions they may charge and the benefit options they may offer. In fact they are so overregulated at present that they have not been able to evolve to keep pace with the changing environment in the South African health sector. It is time that the PMB regulations took these hard facts into account.

Other Principles

1. At a workshop attended by BHF members to discuss draft 3 it was noted that:
 - a. The supported principles are to promote access, equity and affordability. Draft 3 has ignored the principle of equity e.g, limitation on the number of chronic conditions to be covered, selective inclusion of dental cover for pain and infection but not medical i.e. tooth abscess can be covered but not other abscesses treated by a medical practitioner.
 - b. BHF members were not opposed to the inclusion of catastrophic cover to the extent that it can be defined as essential healthcare benefit/service, cost drivers are mitigated against and the package remains affordable.
 - c. BHF members expressed support for the principles included in the BHF submissions.
 - d. Members expressed concern regarding the manner in which the proposed benefits are being forced through under the guise of consultation as all comments that have been submitted, including

some agreed upon principles published in previous drafts, have been ignored by the regulator (déjà vu from late 1990s when DTPs were blindly pushed through).

2. Principles highlighted in the document imply that it is not necessary for private sector beneficiaries to have the same core benefit entitlement as the indigent that use the public sector. This notion is inconsistent with the National Health Act.
 - a. There is an assumption by the regulator that frequently occurring claims of lower cost/price are affordable (figure 4) to the medical scheme membership and can be paid "...on an out-of-pocket or paid from savings". There is no supporting substantiation provided for this assumption.
 - i. This assumption remains the motivation to ensure that high cost low frequency health events are "insured". BHF is not against high cost interventions to the extent that they are proven to be an essential healthcare service and affordability of the benefit package is assured.
 - ii. In draft 3 essential healthcare service definition is a secondary consideration to identify the "catastrophic events" that must be "Insured". To-date, one year since the commencement of the review process, the DTP with its structural problems, considered for continued inclusion as a PMB by the regulator, has not been measured against the definition of essential healthcare provided in Annexure A.
 - b. BHF supports a core common benefit between the private and public sectors, and additional prescribed benefit for the private sector to the extent that the prescribed package of benefits continues to remain affordable to medical scheme members.

3. Recommendation 4.2 of Draft 3 page 12 appears to confirm that the intention of the regulator is to expand the PMB rather than review it. The DTP's have been copied and pasted into the document with minor wording changes. Inconsistencies identified and communicated in previous submissions, and acknowledged by the regulator, have been ignored.
4. In the interest of good governance by the CMS, exemption from PMB provisions for low income options (point 4.3 page 12) should have an associated guiding framework stated to prevent biased application of policy.
5. Draft 3 makes no attempt to address definition problems highlighted in previous submissions. Recommendation 7 of 4.4 on page 13 assumes that the development of comprehensive descriptions is easy for the current disorganized DTP structure. While the intention is noble and supported, the statement trivializes the complexity of the exercise and activity involved. In previous submissions, recommendations were made to avoid reference to levels of severity, as well as terms such as "treatable" and "life threatening" in the DTP's as these pose major definition/description development challenges.
6. BHF supports the definition of essential healthcare to the extent that points a to d are not mutually exclusive i.e. they are read together and that all included PMB benefits must meet all four description requirements. Aligned to BHF's previous submission point e could be added to read "evidence based primary care" to align the definition to the intention of the National Health Act. This point can be read on its own, independent of points a to d.

7. BHF is delighted that the regulator recognizes the need for a negotiated fee for the PMBs. We urge the NDoH to accelerate this process.
8. This PMB review and its implementation must not be independent of factors such as risk equalisation, income cross subsidy nor mandatory membership policy and implementation considerations!

Inconsistencies and contradictions

9. Draft 3 ignores some important comments and principles highlighted in drafts 1 and 2 of the PMB review document, i.e. importance of addressing structural problems and inconsistencies in the interest of equity
 - a. granting benefit for otitis media but ignoring benefit for sinusitis that has a similar pathophysiologic aetiology
 - b. allowing benefit other than medication for rheumatoid arthritis patients but not for patients with osteoarthritis
 - c. structural anomaly related to chronic disease benefit
 - i. The continued perseverance with the CDL list is not adequately explained by the regulator. Furthermore, the origin of this list is based on the most frequent chronic conditions at the time of its introduction and is not sufficiently comprehensive based on the essential healthcare definition provided in annexure A of this draft 3 and BHF's proposed amendment. In the interest of equity, other chronic conditions should also be covered. This can be achieved by avoiding a positive list but specifying a negative list. See BHF proposal (response submission to draft 1) on enhancing access to care to patients with chronic disease in an equitable yet affordable manner.
 - ii. A number of chronic conditions are listed both in the DTP and CDL with the specific intention to assure outpatient

benefit for patients with chronic conditions e.g. coronary artery disease, cardiac failure, arrhythmias etc. However, certain chronic conditions e.g. rheumatic fever and polyarteritis nodosa are listed in the DTP but not in the CDL. While other chronic conditions such as polymyopathy that have comparable autoimmune aetiology as conditions similar to SLE, RA and polyarteritis nodosa is not included in either list. The regulator must have had specific reasons for structuring the benefits in this anomalous and inconsistent manner; perhaps the regulator's intention was not to cover benefit on an outpatient basis for these conditions or it is a reflection of poor judgment in the structural development of the intended DTP/CDL benefit. Based on the Draft 3 content, it appears that this anomaly is to be perpetuated as the regulator has ignored previous submissions and advice in this regard.

- iii. Combination of existing algorithms and an EDL represents duplication and is unnecessary as the EDL is both internationally and locally researched and adopted. It is recommended that the algorithms are avoided/deleted in the revised version of the PMB.
- iv. CDL and its associated algorithms cover a limited number of conditions while the EDL will cover more chronic conditions.
- v. Weakness of the CDL and algorithm was recognised by the outgoing Registrar of CMS at the time when LIMS benefit, containing EDL, was proposed. Furthermore, the implementation of the review of the nine algorithms, included in draft three, was halted over two years ago due to problems with the evaluation process as well as the need to find an improved structure to cover chronic benefits more broadly.

- vi. Notwithstanding the above, there is an imbalance between the count of CDLs proposed and the count of algorithms included in Draft 3. This reflects the error in judgment and the haste in which Draft 3 proposals were put together.
- vii. In the interest of equity and greater access to care, BHF suggests the following:
 - 1. That a chronic benefit is provided without a positive list i.e. all chronic conditions (small negative list provided) enjoy additional benefit
 - a. A proposed negative list, for additional chronic benefit other than for EDL medication, is specified below for discussion.
 - i. Acne
 - ii. Allergy (including allergic rhinitis) and Urticaria
 - iii. Alopecia
 - iv. Corns and callosities
 - v. Dementia
 - vi. Dermatitis and Eczema
 - vii. Gastro-Oesophageal Reflux Disorder (GORD) excluding Barretts
 - viii. Infertility
 - ix. Irritable bowel syndrome and other functional intestinal disorders
 - x. Menopause (HRT related)
 - xi. Osteo-arthritis
 - xii. Peptic ulcers
 - xiii. Prostatic hypertrophy
 - xiv. Vitiligo
 - xv. Others: included in exclusion list of draft 3 and those identified in consultation with health service providers.

2. Drug benefit can be provided from the EDL and/or additional annexure listing other drugs considered important to fund, with specified inclusion and exclusion criteria, including appropriate price for the funding. The additional drugs considered important to fund can be included to the extent that the prescribed benefit package continues to remain affordable.
 3. Use the SA adapted version of the EDL from the SA EDL committee of the NDoH instead of one that is copied and pasted from the World Health Organisation.
- d. EDL is listed in Box 3 on page 19 under out of hospital benefit. However, the EDL list in annexure G and H include inpatient medication as well. It is not clear from this inconsistency how the inpatient drugs listed in the WHO EDL are to be applied to inpatient benefits. Clarity is required. The BHF and its members are not averse to the EDL being applied to inpatient benefit.
- e. The DTPs include items that are not catastrophic or consistent with the definition of essential healthcare provided in Annexure A. This is inconsistent with recommendation 1 of 4.1 on page 12.
- i. Examples
 1. Hypothyroidism listed in the CDL is frequently occurring and low cost therefore by definition published in draft 3 cannot be considered catastrophic; however it is an important clinical condition and an essential chronic condition to fund as a part of the PMB.
 2. "Amenorrhoea" and "menopausal symptoms" are examples that are inconsistent with essential healthcare definition or "catastrophic" conditions.
- f. The DTP contains conditions for which treatment is specified in the exclusion list e.g. "bartholin's abscess". Clarity is required in this regard.

10. Point 5.8 on page 18 refers to the inclusion of hospital benefit (excluding a negative list) and inpatient treatment specified in the DTPs and CDLs. The proposed benefit structure based on service type together with a separately stated and ill defined positive list based on diagnosis results in duplication of benefit specification and may lead to confusion. It appears that the regulator is attempting to cherry pick industry recommendations to expand hospital benefits without adequate consideration being given to appropriate structuring and presentation for implementation.

11. Since the commencement of the review process no effort has been made by the regulator to specifically define benefit entitlement for the DTPs that the regulator wants to retain into the future. A lesson can be learnt from the state of Oregon, from where most of the DTP's originated and is copied for implementation in SA, how a benefit can be specified. A coding cross-map exercise will be required.

12. Point 4 of 5.1 on page 16 referring to the use of evidence based medicine to limit benefits for inclusion:
 - a. Preventative screening benefit for inclusion in the PMB includes recommendations on general check up, screening for prostate and breast cancer and pap smear screening, amongst others. Also included is the screening benefit specified in the optometry benefit. Specified details of these (page 63, 64 and 65) are inconsistent with the screening Task Force recommendations (www.ahrq.gov/CLINIC/uspstfix.htm) that are based on published evidence. BHF is not opposed to preventative care being included in the PMB, but is concerned that adequate literature review and research has not been carried out prior to the publication of Draft

3. Evidence based principle has not been applied to the preventative recommendations listed in draft 3.
 - b. The continued inclusion of interferon for multiple sclerosis is inconsistent with the EBM guiding principle.
13. The inclusion of a bone density scan is inconsistent with the proposed chronic medicine benefit in draft 3. No provision has been made to fund the care that may be required in the event of a positive result. Comments relating to the review of screening benefits in point 12a above are also applicable to osteoporosis screening.
14. Point 5 of 5.1 on page 5 refers to inclusion of benefit where there is "...conditions with low member discretion". However, this filter has not been applied to the existing DTP that continues to include conditions not consistent with this principle.
15. It is important to adequately mitigate against coding manipulation.
16. In draft 3, the dental benefit recommended for inclusion covers mainly pain and infection, which, in principle, is supported by the BHF. However its inclusion appears to be selective and opportunistic in order to expand the PMB, as pain and infection in the medical field is not included other than medications from the EDL. This is iniquitous. The BHF recommendations to include dental and optical benefit in the LIMS process and to this PMB review process is aligned to the inclusion of evidence based and essential primary care benefit as envisaged by the National Health Act, and not as the regulator intends in Draft 3 (expand the PMB).

17. It is not clear if points 1 and 2 of annexure I (exclusions) intend to exclude the procedure or the hospitalisation or the level of care or a combination thereof. Procedures such as cataracts and osteotomies require the use of a theatre and are listed in the DTPs as a PMB benefit. BHF suggests that the intention of the regulator is made clear in order that this component can be appropriately structured and presented.

Specific recommendations/corrections on the Draft 3 published document

18. It is recommended that benefit is limited to one week for DTP code 260S in chapter 14 on page 35.
19. BHF supports the funding of acute medication listed on the EDL when appropriately prescribed as part of access to essential primary care.
20. Inclusion of in hospital benefit, listed in point 4 of annexure A on Page 20, for "... Biologicals" needs clarity and clearer definition.
21. On page 25, Kawasaki disease has been removed. Is this deliberate?
22. Point 1d of Annexure D (dental benefits) provides a new definition of children. It is important to maintain a consistent definition particularly in light of the EDL for children in annexure H.

23. See BHF's draft recommendation on dental benefit in its response to Draft 1 with particular reference to the inclusion of limits. These have been based on wide consultation with providers and dental advisors.
24. Inclusion and implementation of optometry benefit must be subject to the elimination of the existing anomalous pricing for lenses and frames. Members of this profession have not denied the existence of the anomalous pricing to the BHF e.g. 50% discount can be obtained if a person is not on a medical aid or is willing to pay in "Cash", buy one get one free or buy a branded frame and get a pair of prescription sunglasses free.
25. Multifocal lenses cannot be considered to be essential, bifocals are. It is strongly recommended that multifocals are removed from the optical benefit.
26. Annexure 1bii of Annexure F refers to protocols but these protocols are not referenced. Furthermore the antenatal benefit proposed is inconsistent with WHO published guidelines that are internationally adopted. The proposal to impose a limit of 4 consultations may therefore be considered to restrict access and benefit without a costing exercise being carried out. Furthermore, its inclusion here represent duplication as the benefit for maternity is specified in the DTP.
27. BHF supports the notion that antenatal care is a primary care service and function. However, there are circumstances that will require the appropriate intervention of an obstetrician. BHF has identified the conditions and specified these with the relevant ICD-10 codes. The

details can be provided upon request. NB: they are however included in the BHF response submission on draft 1 of the PMB review document.

28. Provision of immunization and contraception material should be made available from the State at State prices through public/private partnership arrangements with GP's. Such arrangements used to be in place a number of years ago.
29. Point 3b on page 65 makes reference to "unlimited". This is unnecessary as PMB is based on first Rand cover and at appropriate levels. Any screening recommendation should be based on best evidence.
30. BHF supports the inclusion of risk management strategies which alleviate some of the problems experienced in the past.
31. Specific EDL comments
 - a. Suggest annexure G and H are combined into a single list. Failing which a definition of children must be provided.
 - b. Use the SA EDL list, developed by SA EDL committee established by the NDoH, which is adapted for local needs.
32. BHF recommends that the liquid based cytology laboratory method for pap smear is listed as a PMB exclusion. This method costs more than double the price of the traditional cytology method and therefore cannot be considered efficient. The technology benefits the laboratory without significant additional marginal benefit for the public. Furthermore, this technology was introduced in the private sector without adequate public needs analysis.

References

- ⁱ Mitchell LE, Adzik NS, Melchionne J, Pasquariello PS, Sutton LN, Whitehead AS, 'Spina Bifida' *The Lancet*, Volume 364, Issue 9448, Pages 1885 - 1895, 20 November 2004
- ⁱⁱ 2006 (2) SA 311 (CC)
- ⁱⁱⁱ 2001 (1) SA 46 (CC)
- ^{iv} See note ii above
- ^v 2006 (4) SA 230 (CC)
- ^{vi} 1997 (3) SA 1012 (CC)
- ^{vii} See note ii above