Prescribed Minimum Benefits – Legal Analysis

The Prescribed Minimum Benefits (PMBs) appear in Annexure A to the Regulations under the Medical Schemes Act. They are prescribed in terms of section 29(1))(o) of the Act which states that schemes must provide in their rules for the scope and level of minimum benefits that are to be available to beneficiaries as may be prescribed. In the Regulations, regulation 8 contains provisions relating to PMBs as follows -

8 Prescribed Minimum Benefits

(1) Subject to the provisions of this regulation, any benefit option that is offered by a medical scheme must pay in full, without co-payment or the use of deductibles, the diagnosis, treatment and care costs of the prescribed minimum benefit conditions.

(2) Subject to section 29(1)(p) of the Act, the rules of a medical scheme may, in respect of any benefit option, provide that-
- (a) the diagnosis, treatment and care costs of a prescribed minimum benefit condition will only be paid in full by the medical scheme if those services are obtained from a designated service provider in respect of that condition; and
- (b) a co-payment or deductible, the quantum of which is specified in the rules of the medical scheme, may be imposed on a member if that member or his or her dependant obtains such services from a provider other than a designated service provider, provided that no co-payment or deductible is payable by a member if the service was involuntarily obtained from a provider other than a designated service provider.

(3) For the purposes of subregulation (2)(b), a beneficiary will be deemed to have involuntarily obtained a service from a provider other than a designated service provider, if-
- (a) the service was not available from the designated service provider or would not be provided without unreasonable delay;
- (b) immediate medical or surgical treatment for a prescribed minimum benefit condition was required under circumstances or at locations which reasonably precluded the beneficiary from obtaining such treatment from a designated service provider; or
- (c) there was no designated service provider within reasonable proximity to the beneficiary's ordinary place of business or personal residence.

(4) Subject to subregulations (5) and (6) and to section 29(1)(p) of the Act, these Regulations must not be construed to prevent medical schemes from employing appropriate interventions aimed at improving the efficiency and effectiveness of health care provision, including such techniques as requirements for pre-authorisation, the application of treatment protocols, and the use of formularies.

(5) When a formulary includes a drug that is clinically appropriate and effective for the treatment of a prescribed minimum benefit condition suffered by a beneficiary, and that beneficiary knowingly declines the formulary drug and opts

to use another drug instead, the scheme may impose a co-payment on the relevant member.

(6) A medical scheme may not prohibit, or enter into an arrangement or contract that prohibits, the initiation of an appropriate intervention by a health care provider prior to receiving authorisation from the medical scheme or any other party, in respect of an emergency medical condition.

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.

Clarity and Certainty

The PMB package is nor clear or 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 muscles 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.

There are two major disorder complexes associated with disease of the basal ganglia and related structures: the parkinsonian syndrome and the choreas. Athetosis and the dystonias, also basal ganglia disorders, are much less common, with the exception of spasmodic torticollis and dystonias produced by certain neuroleptic drugs.

[1]"Parkinsonism" is a relatively common complex of neurologic symptoms that can be seen with many types of extrapyramidal disease. This constellation of symptoms appears as the end product of many degenerative disorders of the brain, although some produce the symptoms much earlier in the course than others. For example, most patients with a generalized dementing condition of the brain will eventually develop symptoms of parkinsonism. However, this occurs quite late in the course of the disease for most of these conditions.

Cerebrovascular disease can also target the extrapyramidal system (especially when diffuse), leading to parkinsonian symptoms.

[2]Extrapyramidal disorders are characterized by the presence in the waking state of one or more of the following features: dyskinesias, athetosis, ballismus, tremors, rigidity, and dystonias. Sydenham chorea is characterized by an acute onset of choreiform movements and variable degrees of psychological disturbance. It is frequently associated with rheumatic endocarditis and arthritis. Chorea has also been associated with hypocalcemia; with vascular lupus erythematosus; and with toxic, viral, infectious, parainfectious, and degenerative encephalopathies. Chorea, or rapid involuntary movements of the limbs and face, is the hallmark physical finding.

[3]Essentially, extrapyramidal disorders can be characterized by symptoms such as involuntary movements (tremors, tics, etc.); impairment of voluntary movement (brady-, hypo-, or akinesia); and changes in muscle tone and posture (dystonia, muscle rigidity, dysequilibrium). Parkinsonism. These disorders may result in the patient's inability to feed himself. It is not clear what is meant by the words "difficulty in …" in Code 213A. It could be that a patient has difficulty in eating because his hands shake so much that he can't feed himself. On the other hand it could mean for instance that he or she has problems with jaw muscles and can't chew properly.

Basal ganglia disorders can be non-progressive[4] therefore satisfying the requirement in Code 213A in the PMBs "due to non-progressive (including spinal) neurological condition".

[5]Fahr's syndrome is a rare neurological disorder characterized by abnormal deposits of calcium in certain of areas of the brain including the basal ganglia and the cerebral cortex. Symptoms of the disorder may include motor function deterioration, dementia, mental retardation, spastic paralysis, dysarthria (poorly articulated speech), spasticity (stiffness of the limbs), ocular (eye) impairments, and athetosis (involuntary, writhing movements). Features of Parkinson's disease such as tremors, rigidity (resistance to imposed movement), a mask-like facial appearance, shuffling gait, and a "pill-rolling" motion of the fingers may also occur in individuals with Fahr's syndrome. Other symptoms may include dystonia (disordered muscle tone), chorea (involuntary, rapid, jerky movements), and seizures. Onset of the disorder may occur at any time from childhood to adulthood. Fahr's syndrome could be covered by Code 213A or Code 341A. If these codes are associated through CPT4 coding with a tariff, the charges might

be very different despite the fact that they could be referring to the same health condition.

Difficulty in breathing, eating, swallowing etc as listed in Code 213A are not diagnoses. They are symptoms of a great number of potential diagnoses that range from injury to various illnesses. In some cases the PMBs refer to actual diagnoses and in other cases they refer merely to symptoms that can be evidence of any number of different diagnoses.

The Merriam-Webster Online Dictionary[6] gives the definition of diagnosis as -

Main Entry: **di·ag·no·sis**
1 a : the art or act of identifying a disease from its signs and symptoms **b :** the decision reached by diagnosis
2 : a concise technical description of a taxon

The Free dictionary[7] defines diagnosis as follows:
di·ag·no·sis
1. *Medicine*
a. The act or process of identifying or determining the nature and cause of a disease or injury through evaluation of patient history, examination, and review of laboratory data.
b. The opinion derived from such an evaluation.

Another definition given by MedicineNet[8] is –

Diagnosis: 1 The nature of a disease; the identification of an illness. **2** A conclusion or decision reached by diagnosis. The diagnosis is rabies. **3** The identification of any problem. The diagnosis was a plugged IV.
The word diagnosis comes directly from the Greek, but the meaning has been changed. To the Greeks a diagnosis meant specifically a "discrimination, a distinguishing, or a discerning between two possibilities." Today, in medicine that corresponds more closely to a differential diagnosis.

A symptom, on the other hand, is something quite different.

In Merriam-Webster Online dictionary it is defined as –

Main Entry: **symp·tom**
1 a : subjective evidence of disease or physical disturbance; *broadly* **:** something that indicates the presence of bodily disorder **b :** an evident reaction by a plant to a pathogen
2 a : something that indicates the existence of something else <*symptoms* of an inner turmoil> **b :** a slight indication

In the Free Dictionary it is defined as -

[9]**symp·tom**
1. A characteristic sign or indication of the existence of something else: *"The affair is a symptom of a global marital disturbance; it is not the disturbance itself" Maggie Scarf.*
2. A sign or an indication of disorder or disease, especially when experienced by an individual as a change from normal function, sensation, or appearance.

MedicineNet[10] defines symptom as follows -

Symptom: Any subjective evidence of disease. Anxiety, lower back pain, and fatigue are all symptoms. They are sensations only the patient can perceive. In contrast, a sign is objective evidence of disease. A bloody nose is a sign. It is evident to the patient, doctor, nurse and other observers.

The conflation of symptoms and diagnoses within the PMBs has the potential to cause confusion and uncertainty. The language used in the PMBs is inconsistent. For example in Code 906A the treatment is given as: "Medical management; ventilation and plasmapheresis" whilst in Code 341A the treatment is given as: "Initial diagnosis, initiation of medical management". The latter suggests that only the *initiation* of medical management as opposed to the full spectrum of medical management is covered. When one considers that the same condition could potentially be described by either Code 906A or Code 341A the result is inconsistency in the treatment that is covered by the PMBs. The term "initiation" of medical management as opposed to just "medical management" occurs

Law that is uncertain is problematic from a constitutional perspective. The rule of law is a constitutional principle. The rule of law requires legal certainty[11]. A regulation can be struck down by a court as void for vagueness[12]. Courts will do their best to give a regulation a meaningful interpretation if they can and it is not suggested here that the PMB regulations as a whole are void for vagueness but they do lack clarity in a number of aspects which are detailed below.

The conflation of diagnoses and symptoms pervades the PMB.

Further examples of this are -

Code: 256A
DIAGNOSIS: Transient cerebral ischaemia;

Cerebral ischaemia is a symptom of other conditions. Common causes of cerebral ischemia include carotid artery stenosis, basilar artery stenosis, vertebral artery stenosis and cerebral occlusive disease. Other rare causes of cerebral ischemia include moyamoya disease and Takayasu's arteritis[13]. Cerebral ischemia is a complex injury process that occurs when the nutrient blood supply to cerebral structures is reduced below critical levels. The causes of cerebral ischemia are protean, but the underlying pathophysiologic mechanism that leads to injury is a mismatch between the supply of nutrients to a given cell (or population of cells) and the demand of the cell(s) for those essential nutrients[14].

Code: 213A
DIAGNOSIS: Difficulty breathing, eating, swallowing, bowel or bladder control due to non-progressive neurological (including spinal) condition or injury.

Code : 1A
DIAGNOSIS: Severe/moderate head injury; hematoma/oedema with loss of consciousness

Also, it is not clear whether the hematoma or oedema in Code 1A must be the result of head injury or whether it stands alone as a separate but related ‘diagnosis’. In other words would hematoma/oedema with loss of consciousness be a PMB in the absence of severe/moderate head injury?

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.

Another good example of significant overlapping between PMB conditions is as follows –

Code: 941A
DIAGNOSIS: Spinal cord compression, ischaemia or degenerative disease NOS

Spinal cord compression can be a symptom of many diagnoses. It could for instance be the result of a vertebral facture, tumour, abscess, ruptured intervertebral disc or degenerative diseases such as arthritis[15].

These causes of spinal cord compression referred to in Code 941A are also covered under -

1. Code: 231A
   DIAGNOSIS: Difficult in breathing, eating, swallowing, bowel or bladder control due to non-progressive neurological (including spinal) condition or injury

2. Code: 211A
   DIAGNOSIS: intraspinal and intracranial abscess

3. Code: 109A
   DIAGNOSIS: Vertebral disclocations/fractures, open or closed with injury to spinal cord

4. Code: 950H
   DIAGNOSIS: Cancer of bones – treatable

5. Code:491H
   DIAGNOSIS: dislocations, fractures of vertebral column without spinal cord injury

Where these different diagnoses are associated with a tariff there may be different charges associated with each and this would encourage gaming of such a tariff by the provider in order to obtain the highest possible fee. It is also confusing for honest providers as to what treatment is covered. Repetition is not a sound principle of legislative drafting as it creates unnecessary confusion in the mind of the reader. To the extent that there is significant repetition within the PMB regulations they need revision in order to ensure legal certainty and clarity.

There is a note 7 to the PMBs which states –

Hospital treatment where the diagnosis is uncertain and/or admission for diagnostic

purposes. Urgent admission may be required where a diagnosis has not yet been made. Certain categories of prescribed minimum benefits are described in terms of presenting symptoms, rather than diagnosis, and in these cases, inclusion within the prescribed minimum benefits may be assumed without a definitive diagnosis. In other cases, clinical evidence should be regarded as sufficient where this suggests the existence of a diagnosis that is included within the package. Medical schemes may, however, require confirmatory evidence of this diagnosis within a reasonable period of time, and where they consistently encounter difficulties with particular providers or provider networks, such problems should be brought to the attention of the Council for Medical Schemes for resolution.

It is submitted that the focus in diagnosis in the PMBs is problematic for the very reasons highlighted in note 7. Although there is a predominant emphasis on diagnosis, the note impliedly acknowledges that the focus is flawed and therefore provision is made in certain instances for prescribed minimum benefit conditions to be identified from symptoms alone. This makes for confusion for instance as to when in fact a condition is a prescribed minimum benefit. Once the symptoms have been stabilised and the underlying condition has perhaps been identified as a non-PMB condition what is the legal position of the scheme? Must it continue to pay the full costs of the treatment ongoing or must it only pay the full costs of the treatment that served to stabilize the symptoms listed as the PMB condition?

Reasonableness

CODE: 905B
DIAGNOSIS: Cancer of eye and orbit – treatable
TREATMENT: Medical and surgical management which includes radiation therapy and chemotherapy.

What does 'treatable' means? Does it mean 'curable' or 'partially curable' or does it mean "palliative care'? Is the intention that if nothing can be done about the cancer then the condition does not fall within the scope of the prescribed minimum benefits package? Health care services are provided not only to 'treat' a condition but to ease discomfort and help the patient cope with the health condition. Not all cancers are terminal so the fact that Code CODE: 260S provides as follows -
DIAGNOSIS: Imminent death regardless of diagnosis
Treatment: comfort care; pain relief; hydration
is no answer to this question.

At the end of the PMBs stands a note 3 concerning treatable cancers as follows -

'Treatable' cancers. In general, solid organ malignant tumours (excluding lymphomas) will be regarded as treatable where:

- i) they involve only the organ of origin, and have not spread to adjacent organs;
- ii) there is no evidence of distant metastatic spread;
- iii) they have not, by means of compression, infarction, or other means, brought about irreversible and irreparable damage to the organ within which they originated (for example brain stem compression caused by a cerebral tumour) or another vital organ
- iv) or, if points i. to iii. do not apply, there is a well demonstrated five year survival rate of greater than 10% for the given therapy for the condition concerned.

It is submitted that this note is problematic because medical science is constantly changing as new treatments are being discovered and new drugs are released onto the market. It is also problematic because it means that a scheme which was previously paying for the 'treatable' cancer may cease to pay for further treatment once it has been decided that it is no longer treatable. The fact that a scheme is required to pay for palliative care is not an answer because palliative care does not include the treatment of cancer with a view to eliminating it. The patient who has been declared untreatable by the private sector could well turn to the public health sector for further treatment of the cancer in the hope of a cure. The power of the State to refuse to render such treatment is limited. The note could be regarded as unconstitutional in that it denies private health care funding to a patient who is desperately ill. The doctors that have treated her in the private sector and who know her medical history will not necessarily be able to treat her in a public health establishment and she could be prejudiced by this fact alone.

Note 4 to the PMBs is also problematic. It reads –

Tumour chemotherapy with or without bone marrow transplantation and other indications for bone marrow transplantation.

These are included in the prescribed minimum benefits package only where Annexure A explicitly mentions such interventions. Management may include a first full course of chemotherapy (including, if indicated, induction, consolidation and myeloablative components). Where specified in terms of Annexure A, this may be followed by bone marrow transplantation/rescue, according to tumour type and prevailing practice. The following conditions would also apply to the bone marrow transplantation component of the prescribed minimum benefits:

i) the patient should be under 60 years of age
ii) allogeneic bone marrow transplantation should only be considered where there is an HLA matched family donor
iii) the patient should not have relapsed after a previous full course of chemotherapy
iv) (points i. and ii. shall also apply to bone marrow transplantation for non-malignant diseases).

This note may be unconstitutional insofar as it restricts the age of the patient to less than 60 for a bone marrow transplant. The Minister of Health who is over sixty recently had a liver transplant.

The statement in note 5 on solid organ transplants is also too narrow. It is possible to obtain a private donor of certain organs – for instance a portion of the liver or a kidney. The donor is only prepared to make the donation to the specific patient usually by virtue of a family or spousal relationship between them. The restriction may be unconstitutional in such circumstances as it could be tantamount to a denial of access to a health care service. The note states that the prescribed minimum benefits Annexure includes solid organ transplants (liver, kidney and heart) only where these are provided by Public hospitals in accordance with Public sector protocols and subject to public sector waiting lists.

Yacoob J in Government of the *Republic of South Africa and Others v Grootboom and Others*[16] stated the test of reasonableness as follows:

'Reasonableness must also be understood in the context of the Bill of Rights as a whole. The right of access to adequate housing is entrenched because we value human beings and want to ensure that they are afforded their basic human needs. A society must seek to ensure that the basic necessities of life are provided to all if it is to be a society based on human dignity, freedom and equality. To be reasonable, measures cannot leave out of account the degree and extent of the denial of the right they endeavour to realise. . . . Furthermore, the Constitution requires that everyone must be treated with care and concern. If the measures, though statistically successful, fail to respond to the needs of those most desperate, they may not pass the test.'

It is submitted that due to the State's constitutional obligation to take reasonable legislative and other measures to ensure the progressive realisation of the right of access to health care services, health legislation in particular must always be tested against this standard. In the case of the PMB package it covers many health conditions that are rare and unlikely to occur at the expense of those that are very common and highly likely to occur. The government has identified primary health care as a focal point for health service delivery in South Africa but the PMB package does not reflect this at all. It is suggested that the PMB does not pass the test of reasonableness as elucidated by Yacoob J and is not a legislative measure designed to improve access to health care services in terms of section 27 of the Constitution.

The World Health Organization defines primary health care as "the principal vehicle for the delivery of health care at the most local level of a country's health system. It is essential health care made accessible at a cost the country and community can afford with methods that are practical, scientifically sound and socially acceptable. Everyone in the community should have access to it, and everyone should be involved in it. Beside an appropriate treatment of common diseases and injuries, provision of essential drugs, material and child provision of essential drugs, maternal and child health, and prevention and control of locally endemic diseases and immunization, it should also include at least education of the community on prevalent health problems and methods of preventing them, promotion of proper nutrition, safe water and sanitation."[17]

Inconsistencies

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

Glaucoma

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[18].

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 is published in the August issue of *Archives of Ophthalmology*[19].

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.[20].

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[21].

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 minumum 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: Trabulectomy; other surgery.

It is submitted that this inappropriate focus on surgical interventions as oppose to non-surgical 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 it 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.

To compound the confusion around glaucoma even further, it is included as a chronic disease in the list that appears in the regulations after the Diagnosis-Treatment pairs. What is the point of including glaucoma in this list if it already appears in three different places in the list of DTPs? The treatment specified for all of the chronic conditions listed in the regulations in the DTPs includes surgery and, except for Code 405B, also includes medical management. It is not clear why medical management was omitted from Code 405B since it is conceiveable that disorders of the lens might also require such treatment.

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

CODE: 407B
DIAGNOSIS: PRIMARY AND OPEN ANGLE GLAUCOMA WITH FAILED MEDICAL MANAGEMENT
TREATMENT: TRABECULECTOMY; OTHER SURGERY

In the chronic conditions list the treatment is specified for all of the chronic conditions as: "Diagnosis, medical management and medication, to the extent that this is provided for by way of a therapeutic algorithm for the specified condition, published by the Minister by notice in the Gazette."

It is not clear whether the "treatment" specified in the chronic conditions list is over and above the treatment specified in the DTPs or whether it is only for those cases not specifically covered in the DTPs eg. secondary glaucoma.

Inconsistencies such as those highlighted above are likely to cause the failure of the PMB regulations of a reasonableness test. The more arbitrary the PMBs appear, the more likely they are to fail a test of reasonableness and be struck down as unconstitutional. Unfair discrimination is also prohibited in terms of the Constitution. Even if the PMBs are only indirectly unfairly discriminatory they are unlikely to pass constitutional muster. Why should disorders of the lens not be managed medically under the PMBs when all of the other glaucomas are? What about the potential overlap of the diagnosis in Code 405B with those in Codes 394B and 407B?

Constitutionality

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.

Take for example :
Code: 47B
DIAGNOSIS: Acute Orbital Cellulitis

Acute orbital cellulitis[22]

Roentgenograms showed paranasal sinus in 77 of 91 patients. Haemophilus influenzae and Diplococcus pneumoniae were recovered from the blood of 20 and 6 patients, respectively. Four children had concomitant H influenzae meningitis. Bacteremia was demonstrated in 29% and more common in those with extensive orbital involvement, those not receiving antibiotics at the time of culture, and those less than 2 years old. Some of the 26 patients with less extensive involvement were bacteremic (17%), had leukocytosis, or roentgenographic evidence of sinusitis. Most children received large doses of ampicillin sodium and methicillin sodium intravenously until signs and symptoms had almost abated. With this regimen, there were no orbital, ocular, or other complications.

[23]Sinus disease was found to be the commonest cause of orbital cellulitis, with the commonest organism being *Streptococcus milleri*. Only 50 per cent of cases with proven

disease had had a raised white cell count; this is therefore not a very sensitive test. Most orbital cellulitis therefore seems to have its origins in sinus infections which, if treated at primary care level, would obviate the need to treat acute orbital cellulitis.

Sinus disease does not appear to be a prescribed minimum benefit condition. Orbital cellulitis, which is the result of an underlying condition, is treatable under the PMBs but the underlying condition itself is not. If the patient does not have the funding to treat the underlying condition then he runs the risk of the recurrence of the orbital cellulitis. This is contrary to the principle of primary health care endorsed by the South African government in the National Health Act and elsewhere. Section 3 of that Act states that the Minister must, within the limits of available resources ensure the provision of such essential health services, which must at least include primary health care services, to the population of the Republic as may be prescribed after consultation with the National Health Council.

Anaerobic conditions are covered in Code 277S but only if they are life-threatening -

CODE: 277S
DIAGNOSIS: Anaerobic infections - life-threatening
Treatment: medical management; hyperbaric oxygen

The question is what does 'life-threatening' mean? At what stage does an anaerobic infection become 'life-threatening' as presumably not all anaerobic infections are life-threatening? This terminology is very vague and open to interpretation which means it is uncertain in law what exactly is covered under the PMBs and what is not.

Many of the PMB conditions are rare. They are thus unlikely to occur. This reflects the catastrophic insurance centred approach of the PMBs. As such the PMBs do not support the principles of access, equity and affordability. They are not concerned with the overall state of health of the patient – only coverage by the medical scheme of certain high cost interventions. This is in marked contrast to government policy and indeed the constitutional obligation of the state to ensure the progressive realisation of the right of access to health care services.

What the current PMBs seem effectively to be saying is that if you happen to get a fairly rare but very serious health condition you will be covered, in some cases, provided that the condition reaches a particular point of severity. The cover is expensive because although the risks may in many instances be low in terms of frequency, the cost is high when the risk materializes and the scheme has no choice but to pay. This creates a tendency for schemes not to pay for medical management of conditions that may underlie or give rise to a prescribed minimum benefit condition because their focus is on the PMB condition and providing for the associated risks. The understanding is that the scheme will pay only if you as a member are very very sick. This is in direct contrast to the medical schemes paradigm which is not that of the insurance industry, to the effect that claims against the scheme are the rule rather than the exception. Being a member of a medical scheme means that one expects the costs of the use of health care services to be defrayed regardless of the reason for the need for those services.

Medical scheme cover is not dreaded disease insurance. The latter can be purchased through an insurance policy at a much more competitive rate than the cost of medical

scheme membership. However the PMB conditions would seem to favour the dreaded disease approach to funding of health care services.

Many of the PMBs specify that the condition must be 'treatable' and the meaning of this word has already been queried. However there is one aspect that has not been raised. What happens if the condition is being treated as a PMB condition and then it is decided that it has become or is in fact 'untreatable' since there appears to be no healing or recovery taking place? Does the condition remain a PMB condition or does it fall out of the PMBs? If so does treatment cease if the patient has no other source of funding?

There are significant ethical and legal dilemmas when it comes to cessation of treatment for a condition that was previously treated. At what stage exactly does a patient become 'untreatable'? Is it when his doctor says he is untreatable or when a doctor who is asked for a second opinion agrees that he is untreatable? Does it mean untreatable in South Africa or untreatable throughout the world? In other words does the fact that the technology necessary to treat the patient not available locally render his condition untreatable?

By way of example, cancer of the prostate gland can progress very slowly. In most cases the patient is more likely to die of old age than prostate cancer.

It is a PMB condition in terms of Code 953L which reads –

DIAGNOSIS: Cancer of prostate gland – treatable
Treatment: Medical and surgical management, which includes chemotherapy and radiation therapy.

Millions of men have early stage prostate cancer without ever realising it. Autopsy results on men over the age of 80 reveal that 75 percent show evidence of prostate cancer[24]. Prostate cancer is a common cancer in older men. Every year in the UK about 22 000 men are diagnosed with prostate cancer. About 8 in 10 cases occur in men over the age of 65. It is rare in men under 50. Unlike many other cancers, prostate cancer is often present for years without you realizing it. This is because in many cases the cancer is slow growing and can take many years to cause any symptoms. By the age of 80, more than half of all men will have some cancer cells in their prostate - but only 1 in 30 of them will actually die from it.

Does 'treatable' mean that where a provider decides that the time is not yet ripe to treat a man for prostate cancer, his condition is still 'treatable' in the sense intended in the PMBs or is it presently 'untreatable' but may subsequently become 'treatable' at some future time? What about treatments that can't cure a cancer but can arrest or retard its development? Do these treatments fall within the scope of the term 'treatable' in the PMB regulations or not?

According to the PMB regulations the note on 'Treatable' cancers reads:

"In general, solid organ malignant tumours (excluding lymphomas) will be regarded as treatable where:

i) they involve only the organ of origin, and have not spread to adjacent organs

ii) there is no evidence of distant metastatic spread;

iii) they have not, by means of compression, infarction, or other means, brought about irreversible and irreparable damage to the organ within which they originated (for example brain stem compression caused by a cerebral tumour) or another vital organ;

iv) or, if points i. to iii. do not apply, there is a well demonstrated five year survival rate of greater than 10% for the given therapy for the condition concerned.

In the case of prostate cancer points (i)(ii)(iii) and (iv) may all be applicable but in the view of the medical specialist the cancer is not presently treatable in the sense that there is no point in treating it at its current stage. Treatment of prostate cancer immediately following diagnosis of the condition is not necessarily sound clinical practice[25]. It is submitted that the degrees of severity within the PMB when referring to diagnoses are not in keeping with the constitutional concept of access to health care services. If it is the policy behind the current design of the PMB package to keep high cost cases out of public hospitals in other words, to prevent 'dumping' of patients by medical schemes on public hospitals, then one must ask whether this is a constitutionally valid policy.

Medical schemes are private entities that provide health care funding to their members on a voluntary basis. Membership of a medical scheme is not compulsory. If a person decides not to be a member of a medical scheme, he or she still has a constitutional right of access to health care services and if he or she cannot afford such services, as is likely in the case of catastrophic health conditions, then he or she has a constitutional right to access that health care at a public health establishment. Similarly if a medical scheme member can only afford limited health care cover and opts for cover of expenses that he or she is more likely to incur as opposed to catastrophic based cover, this is an entirely rational personal business decision. If his medical scheme cover runs out or does not extend to a catastrophic condition, this is not deliberate dumping of the patient by a medical scheme onto the public health sector. It is due to an economic fact that the patient could not afford cover for both his non-catastrophic and catastrophic health needs. His right of access to health care services from the state for a catastrophic condition is no less than that of the person who could not afford private medical funding at all.

If the State's insistence via regulations on the purchase of predominantly catastrophic cover means that the member of a medical scheme who cannot afford both non-catastrophic and catastrophic cover must opt for the latter, and this insistence significantly reduces access to health care services in that fewer people are able to buy access to cover for health care services generally, then the policy could well be unconstitutional. If the PMB package is so expensive that it is effectively a barrier to medical scheme cover for middle and low income earners then it is not fulfilling the State's obligation to take legislative and other measures to ensure the progressive realisation of the right of access to health care services, especially in an environment where the State is not in a position to provide health care services to everyone.

Moreover the State's attempts to stop the 'dumping' of high cost patients on public health establishments could result in greater numbers of people being generally dependent on the State for all of their health care needs. It is therefore likely to see more

even people in public sector hospitals for both catastrophic non-catastrophic conditions because they cannot afford to join medical schemes. Does the current structure of the PMB package effectively deny access to adequate health care services at this macro-level? It is submitted that the answer is yes and that for this reason, the structure of the PMB package could be attacked on constitutional grounds. The obligation of the State in terms of section 27 of the Constitution is not to provide health care services to everyone, it is to take legislative and other measures to *ensure* that the right to access is progressively realised. One of the most obvious ways of doings this is to make medical scheme membership more accessible.

Chronic conditions

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, epilepsym, 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.

Conclusion

The prescribed minimum benefits regulations need an extensive overhaul. Government policy is not currently reflected in their orientation towards referred health care services and benefits for catastrophic conditions. People need health care services for any number of health conditions that are not of sufficient severity to qualify as prescribed minimum benefits. The current structure of the PMBs is directly responsible for the high costs of hospital based health care and also discourages rational provision and use of health care resources within the private health sector.

---

1 http://www.dartmouth.edu/~dons/part_2/chapter_18.html

2 http://www.accessmedicine.com/content.aspx?aID=2351303

3 http://www.freepatentsonline.com/4438119.html

4 Paul D. Cheney 'Pathophysiology of the corticospinal system and basal ganglia in cerebral palsy' Mental Retardation and Developmental Disabilities Research Reviews Vol 3 Issue 2 http://www3.interscience.wiley.com/cgi-bin/abstract/56687/ABSTRACT?CRETRY=1&SRETRY=0

5 http://cureresearch.com/artic/ninds_fahr_s_syndrome_information_page_ninds.htm

6 http://m-w.com/dictionary/diagnosis

7 http://www.thefreedictionary.com/diagnosis

8 http://www.medterms.com/script/main/art.asp?articlekey=2979

9 http://www.thefreedictionary.com/symptom

10 http://www.medterms.com/script/main/art.asp?articlekey=5610

11 *Daniels v Campbell NO and Others* 2004(5) SA 331 (C)

12 See *Durban Add-Ventures Ltd v Premier, Kwazulu-Natal, And Others* (No 2) 2001 (1) SA 389 (N) whether the court stated: It is trite that delegated legislation may be set aside on review if it is vague and uncertain. It will, however, only be set aside if it is not reasonably capable of meaningful construction. The Courts have frequently emphasised that 'the law requires reasonable and not perfect lucidity'. (*R v Pretoria Timber Co (Pty) Ltd and Another* 1950 (3) SA 163 (A) at 176H.) The test whether a sufficient degree of clarity has been achieved is provided by the reasonable person. The principle was expressed as follows in *R v De Villiers* 1955 (3) SA 403 (C) at 406B - D:

'While it is the duty of the Court to construe the bylaw or regulation "with no bias towards 'benevolence' " it must, nevertheless, not do so on the basis that it is dealing with capricious or foolish people. It must approach the construction of the bylaw from the angle that it is dealing with reasonable people; in other words, the enquiry must be whether the bylaw gives, with reasonable certainty, sufficient guidance to a reasonable person.'
Recently the Constitutional Court was called upon to decide whether the terms of reference of a commission which had been established by the President were void for vagueness. The Constitutional Court formulated the applicable test as follows:
'Terms of reference constitute a mandate for the commissioner which he or she uses as a guide to determine the scope of his or her investigation. Consequently, the question to be answered is whether objectively the terms of reference are reasonably comprehensible to the commissioner and affected parties so as to determine the nature and ambit of the commissioner's mandate with reasonable certainty.'
(*President of the Republic of South Africa and Others v South African Rugby Football Union and Others* 2000 (1) SA 1 (CC) (1999 (10) BCLR 1059) in para [229].) The test to be applied in this case is whether the new regulations provide, with reasonable certainty, adequate guidance from the perspective of a reasonable person.

13 http://cgi.stanford.edu/~amlin/cgi-bin/find_specialist?action=get_description&disease=cerebralischemia

14 http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=2701376&dopt=AbstractPlus

15 http://www.ubneurosurgery.com/handler.cfm?event=practice,template&cpid=17055

16 2001 (1) SA 46 (CC) (2000 (11) BCLR 1169) [44]

17 http://www.phac-aspc.gc.ca/sdh-dss/glos_e.html

18 http://www.eyecareamerica.org/eyecare/conditions/glaucoma/index.cfm

19 http://www.nlm.nih.gov/medlineplus/print/news/fullstory_53456.html

20 http://www.eyemdlink.com/Condition.asp?ConditionID=2

21 http://www.nlm.nih.gov/medlineplus/ency/article/001620.htm

22 E. C. Watters, P. H. Wallar, D. A. Hiles and R. H. Michaels Archives of Ophthalmology Vol. 94 No. 5, May 1976

23 Journal of Laryngology and Otology Investigation and management of adult periorbital and orbital cellulitis A Robinson , T Beech , A L McDermott and A Sinha

24 http://www.health24.com/medical/Condition_centres/777-792-802-1632,14168.asp

25 John W. Sharp 'Expanding the definition of quality of life for prostate cancer' *Cancer* Vol 71, Issue S3, 1078-1082