

# Heart failure and “payment in full”: What does the law say?

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## LEGISLATIVE AND CONSTITUTIONAL BACKGROUND FOR PMBS

The South African Constitution<sup>(1)</sup> is the highest law in the land, also called the “rule of law”.<sup>(2)</sup> This means that all laws, and the application thereof, should be undertaken in a manner that is consistent with the Constitution (sections 1(c) and 7). The Constitution also requires in specific sections of “the state” to draft legislation or to take other measures to ensure that the constitutional commitments are fulfilled. The Bill of Rights contained in Chapter 2 of the Constitution<sup>(1)</sup> contains one such section, in which two aspects pertain to healthcare, viz. access to healthcare and access to financing.

**Section 27 reads as follows:**

- (1) *Everyone has the right to have access to:*
- (a) *health care services, including reproductive health care;*
  - (b) *sufficient food and water and*
  - (c) *social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.*
- (2) *The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.*
- (3) *No one may be refused emergency medical treatment.*

From the rights contained in section 27(1)(1) - access to healthcare and section 27(1)(c) - legislation such as the Medical Schemes Act

## ABSTRACT

**One of the major practical manifestations of health law and ethics for practitioners in private practice occurs in their interactions with medical schemes. This article sets out the complete legal framework applicable to medical schemes cover as a manifestation of the human right of access to healthcare and the right of access to social security. It is proposed that the legal framework can and should be used as neutral ground so as to ensure that patients obtain funding that provides meaningful cover of the costs of appropriate care.** SAHeart 2013;10:532-537

No 131 of 1998 finds its constitutional roots. Section 27(2) compels the state to make legislation (and institute other measures) so as to “progressively realise” access to healthcare, as well as social security measures (such as subsidised public healthcare and private health insurance mechanisms).

Understanding these constitutional roots of medical schemes legislation is imperative, as it sets the medical schemes dispensation apart from that governing short- and long-term insurance, as governed by other Acts of Parliament.<sup>(3)</sup> Whereas “ordinary” insurance mechanisms can risk-rate, discriminate between individuals on their health status and/or payment made, refuse to pay on the basis of its contract with a person and so forth, medical schemes are by law prohibited from undertaking many of these very common insurance measures.<sup>(4)</sup> Whereas ordinary insurance instruments may exclude cover for certain events, or may require co-payments, the Medical Schemes Act compels the provision of prescribed levels of care for prescribed conditions, irrespective of scheme option, contributions or health status.<sup>(5,6)</sup>

The legal basis for the existence of medical schemes therefore lies, at least in part, within the ambit of section 27(1)(c) (i.e. social security law)<sup>(7)</sup> and not in insurance law. This means that a common risk pool is created from which all of the conditions prescribed<sup>(5)</sup> must be funded for all patients with those conditions. Unlike the case with normal insurance, a beneficiary can therefore not “run out of funds” as more than his/her own contributions are used to cover the specific condition.

The objective of these compulsory benefits are clearly stated in a “preamble” to Annexure A to the General Regulations.<sup>(6)</sup>

*The objective of specifying a set of Prescribed Minimum Benefits within these regulations is two-fold:*

- (i) *To avoid incidents where individuals lose their medical scheme cover in the event of serious illness and the consequent risk of unfunded utilisation of public hospitals.*
- (ii) *To encourage improved efficiency in the allocation of Private and Public health care resources.*

The above means that medical schemes have to fund certain conditions, so as to prevent an additional burden being placed on the public sector. The social security principle is that a person should not be allowed to double-dip, and that if the social security mechanism is a medical scheme, the scheme should cover the materialisation of the risk.<sup>(7)</sup> If the mechanism is the publicly (tax) funded state sector, treatment should be funded there.

The use of the word “unfunded” in the rationale for the PMBs, as set out in Annexure A, is illustrative - it appears to envisage the use of the public sector by medical schemes, but such utilisation would have to be paid for. The level of payment occurs according to the Uniform Patient Fee Schedule, as annually published by the National Department of Health.<sup>(8)</sup> However, in reality those fees are still in fact being cross-subsidised by tax monies and therefore is, in all likelihood, still in contravention of the “double-dipping” social security law principle. Medical scheme reimbursement for compulsory benefits would therefore be, at least in part, subsidised by tax money, and in particular monies ear-marked for the provision of public health services.

## COMPULSORY BENEFITS: THE PRESCRIBED MINIMUM BENEFITS

Prescribed Minimum Benefits (PMBs) are conditions and general descriptions of treatment listed in the regulations to the Medical Schemes Act under the authority of specific sections in the Act.<sup>(5)</sup> In terms of regulation 8, all medical schemes on all options must ensure that the treatments required for these conditions are covered.<sup>(6)</sup>

In spite of being listed and described in a particular fashion, regulation 8 states that the “diagnosis, treatment and care” costs of the PMBs must be funded “in full and without co-payment”.<sup>(6)</sup> This means that all diagnostic tests relating to a PMB, all treatment and all care (e.g. occupational therapy and physiotherapy) must be funded. Regulation 8(5) uses the phrase “clinically appropriate” treatment.<sup>(6)</sup>

When requiring adherence to the legal framework, in view of ensuring compliance with it, as is required by both the Medical Schemes Act<sup>(9)</sup> and the Constitution,<sup>(1)</sup> medical schemes should be made aware that:<sup>(6)</sup>

- a patient's condition is indeed a PMB condition;
- the treatment proposed is clinically appropriate and
- in principle, the diagnosis, treatment and care must be funded in full.

## HEART CONDITIONS AS PMBs

Heart failure is a PMB condition (listed in the regulations<sup>(6)</sup> under the Code “204E”). It is also listed as a Chronic Condition in the so-called CDL – Chronic Disease List.<sup>(6)</sup>

The ICD10 codes listed in the CDL include I50 Heart failure, I50.0 Congestive heart failure, I50.1 Left ventricular failure, I50.9 Heart failure, unspecified, I11.0 Hypertensive heart disease with (con-gestive) heart failure, I13.0 Hypertensive heart and renal disease with (congestive) heart failure and I13.2 Hypertensive heart and renal disease with both (congestive) heart failure and renal failure.<sup>(10)</sup>

The PMB list contains descriptions of care that should be covered in full.<sup>(6)</sup> One of the key gaps in the regulations is the emphasis on medicine as treatment in regulation 8(5)<sup>(6)</sup> and the lack of mention of medical devices. This is in spite of the fact that the principle of clinical appropriateness should find equal application, irrespective of whether the treatment is medical or surgical (or somewhere in-between).<sup>(6)</sup> Annexure A does, however, make differentiations in instances where it describes care to be provided as “medical management” and/or “surgical management”.<sup>(6)</sup> However, regulation 8(1) (the “payment in full” rule) does not delineate treatment to either medical or surgical.<sup>(6)</sup>

According to Annexure A to the regulations, the PMBs are to be reviewed every two years as, according to the law, there is “constant change in medical practice and available medical technology”.<sup>(6)</sup> This review has, however, not happened in any systematic or regularised fashion, meaning that many of the general descriptions in the PMB list and the treatment algorithms that accompany the PMB CDLs have not kept pace with medical practice and technological developments. The failure of the Department of Health to ensure that this takes place could render it open to legal scrutiny and an order could be obtained compelling such a review to take place.

## MEDICINES AND MEDICAL DEVICES ARE INCLUDED IN PMB TREATMENT, IN- AND OUT OF HOSPITAL

In Circular 10 of 2013 the Council for Medical Schemes (CMS) indicated that it “has received several complaints from beneficiaries of medical schemes indicating that their respective medical schemes refuse to pay for medicine and appliances needed by these beneficiaries relating to a prescribed minimum benefit (PMB) condition upon their discharge from hospital. Some medical schemes pay for these benefits from the member’s personal medical savings account.”<sup>(11)</sup>

This circular confirms another key principle found in the explanatory notes to Annexure A of the regulations, that the setting within which PMB care is delivered is not relevant, it can be in- or out of hospital, during or after a hospital stay.<sup>(6)</sup> The only criterion is that the setting is appropriate and, for medicine and device choices, that it complies with the managed care regulations.<sup>(6)</sup>

## WHAT ABOUT COSTS?

Medical schemes have to make decisions as to whether they would fund a particular treatment or not based on what the law prescribes<sup>(6,9)</sup> considering the financial aspects thereof. These tools for managing the financial implications of funding the PMBs are stipulated in regulation 8:<sup>(6)</sup>

- Schemes may appoint service providers as “designated” (DSPs) to render agreed services at an agreed, pre-determined price.
- Schemes may embark on managed care initiatives, such as implementing formularies, treatment protocols and disease caps.

The managed care provisions<sup>(12)</sup> also apply to non-PMB conditions that the scheme undertakes to fund. What is important is that these mechanisms can only be exercised within the ambit of the regulations to the Medical Schemes Act.<sup>(6)</sup> This means that the process of limiting patient (beneficiary) rights of access to healthcare and access to social security (as is guaranteed in section 27)<sup>(1)</sup> has to be transparent and based on criteria set by the law.

## CRITERIA APPLICABLE TO MANAGED CARE Managed care: what schemes should be doing

The first criterion on which managed care interventions should be based relates to the definition of managed care. The law defines managed care as “clinical and financial” management according to rules-based programmes.<sup>(12)</sup> The law therefore stipulates that

scheme reimbursement decisions are not only “funding decisions”, they must also be decisions that relate to the clinical situation of the patient.

This is also the reason why a scheme cannot just say that something is not permitted under its rules. The rules itself must comply with the law.<sup>(9,13)</sup> The rules may simply not be able to cater for exceptional cases where the law requires such patients to be accommodated.

Regulation 15 defines rule-based programmes that schemes must use as a “set of formal techniques designed to monitor the use of, and evaluate the clinical necessity, appropriateness, efficacy, and efficiency of, health care services, procedures or settings, on the basis of which appropriate managed health care interventions are made”.<sup>(12)</sup>

This means that scheme choices to fund, or not to fund a particular treatment for a condition it states that it will cover (or which the law requires coverage for),<sup>(6)</sup> will be measured against the four principles of clinical necessity, appropriateness, efficacy and efficiency.

The CMS Appeal Committee has in the past ruled that the mere fact that the scheme’s rules prefer one alternative treatment or surgical intervention above another does not mean in itself that the scheme had indeed evaluated the alternative according to these criteria.<sup>(14)</sup> The scheme must prove how it had undertaken this.<sup>(14)</sup>

## Evidence-based medicine<sup>(12)</sup>

The importance of setting all funding decisions on the basis of evidence-based medicine was recently confirmed in a Final Appeal Board decision against a medical scheme.<sup>(15)</sup> The Final Appeal Board of the Council for Medical Schemes confirmed that schemes should, up front, set their treatment protocols and formularies on the basis of evidence-based medicine.<sup>(15)</sup> The scheme must also up front anticipate exceptions (e.g. where patients do not respond on the scheme-proposed treatment, or where there is a likelihood of harm etc.) and provide for such cases in their protocols and formularies.<sup>(15)</sup>

This means that the evidence must also be available right from the start, and cannot be submitted only at some stage during a CMS complaints or appeals process. The evidence should be available and should have been considered when the scheme made the original decision to fund, or not to fund, a particular type of intervention.<sup>(15)</sup>

Regulation 15 defines evidence-based medicine as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of beneficiaries whereby individual clinical experience is integrated with the best available external clinical evidence from systematic research”.<sup>(12)</sup>

The scheme has to apply this up front, i.e. patients and providers should know that scheme limitations and permissions are based on sound evidence.<sup>(12)</sup> It is furthermore the duty of the scheme (and not that of the CMS) to set and justify interventions on this basis: “It fell upon the registrar’s office to provide a study on the effectiveness and affordability ... But the scheme’s position on these issues remains undocumented and therefore unverifiable. The decision to decline ... is that of the scheme, not of the registrar’s office. It is thus from the scheme that one would expect a documented clinical evidence-based study ... on which such a decision is predicated.”<sup>(16)</sup>

Regulation 15 requires, within what constitutes evidence-based medicine, that the scheme may “take into account” cost-effectiveness and affordability.<sup>(12)</sup> These factors can however not override evidence-based medicine. The law does not say “provided that” it is cost-effective and affordable. To have cost-effectiveness override evidence-based medicine would mean that certain patients with PMB conditions who are not treated or who are not getting better on the average type of treatment, would not have any PMB rights, as the clinically appropriate treatment for them would be deemed unaffordable and/or cost-ineffective. This would also mean that the most vulnerable patients, who require better or more care, are denied such care. This would be a serious violation of the rights of access to healthcare for those who need it most.

When addressing medical schemes on these matters it is important to point out that the objective is not to treat all patients with a particular condition as if they needed the exceptional treatment. Evidence-based medicine will still dictate that patients start with treatment according to recognised treatment protocols and/or formularies.<sup>(12)</sup>

## WHAT THE LAW SAYS ABOUT EXCEPTIONS

Regulations 15H (protocols) and 15I (formularies) to the Medical Schemes Act explain the exceptional circumstances where the scheme should pay in full for an alternative to the scheme-required treatment:

**15H. Protocols.** *If managed health care entails the use of a protocol:*

(a) such protocol must be developed on the basis of evidence-based medicine, taking into account considerations of cost-effectiveness and affordability;

(b) the medical scheme and the managed health care organisation must provide such protocol to health care providers, beneficiaries and members of the public, upon request and

(c) provision must be made for appropriate exceptions where a protocol has been ineffective or causes or would cause harm to a beneficiary, without penalty to that beneficiary.

**15I. Formularies.** *If managed health care entails the use of a formulary or restricted list of drugs:*

(a) such formulary or restricted list must be developed on the basis of evidence-based medicine, taking into account considerations of cost effectiveness and affordability;

(b) the medical scheme and the managed health care organisation must provide such formulary or restricted list to health care providers, beneficiaries and members of the public, upon request and

(c) provision must be made for appropriate substitution of drugs where a formulary drug has been ineffective or causes or would cause adverse reaction in a beneficiary, without penalty to that beneficiary (emphases provided).<sup>(12)</sup>

The interpretation of these provisions is plain: if these circumstances (ineffectiveness, cause or likely cause of harm, adverse reaction) are in existence the scheme cannot require the patient to co-pay to access appropriate care.

## APPLYING THE LAW TO ACT IN THE PATIENT'S BEST INTEREST

Medical practitioners are under an ethical duty to act in their patients’ best interests. This means understanding and applying medical schemes legislation to concrete cases.

The first important application of the law is indicating the patient’s condition is a PMB condition and referring to the legal requirement that PMBs should be funded in full. This has to be indicated with reference to both the conditions PMB Code as well as the ICD-10 code.<sup>(6,10)</sup>

Secondly, all motivations (for both PMBs and non-PMBs) must address the legislated evidence-based medicine requirement, in particular talking about the individual patient, and how s/he fits into the scientific profile as established by the “best available external evidence”.<sup>(12)</sup>

On the matter of clinical appropriateness, which is a requirement of regulation 8(5) and regulation 15, listing the symptoms, results of tests and the patient’s condition is not enough – a direct link must

be made between the patient's condition and what the evidence says about a patient in that position.<sup>(6,12)</sup> If the motivation leaves doubt as to whether the proposed treatment is the correct or even the only clinically appropriate alternative for the patient, the scheme would be justified in denying authorisation.

A good motivation will also point out explicitly whether there has been treatment failure, adverse events and/or the likelihood of harm.<sup>(12)</sup> Most importantly, should the above case be made out, the patient may not be expected to make a co-payment and it is recommended that practitioners inform patients of this.

## THE PROCESS AFTER A MOTIVATION

Practitioners would normally motivate and follow-up or dispute the outcome of a motivation telephonically. When doing so, the provisions of regulation 15D are important (emphases provided):

*“(b) the managed health care programmes use documented clinical review criteria that are based upon evidence-based medicine, taking into account considerations of cost-effectiveness and affordability, and are evaluated periodically to ensure relevance for funding decisions;*

*(c) the managed health care programmes use transparent and verifiable criteria for any other decision-making factor affecting funding decisions and are evaluated periodically to ensure relevance for funding decisions;*

*(d) qualified health care professionals administer the managed health care programmes and oversee funding decisions, and that the appropriateness of such decisions are evaluated periodically by clinical peers”.*<sup>(12)</sup>

Should a satisfactory resolution not be reached, the patient can lodge a complaint at the Council for Medical Schemes (CMS) at fax: 012 431 0608 or email [complaints@medicalschemes.com](mailto:complaints@medicalschemes.com).<sup>(17)</sup>

In law, to make out a good case it is important that the patient or provider should attach all correspondence (including the doctor's motivation and the scheme's response), any notifications, emails, marketing materials, formularies etc. to the complaint.

The Medical Schemes Act prescribes the following procedure in section 47:<sup>(9)</sup>

### 47. Complaints.

*(1) The Registrar shall, where a written complaint in relation to any matter provided for in this Act has been lodged with the Council, furnish the party complained against with full particulars of*

*the complaint and request such party to furnish the Registrar with his or her written comments thereon within 30 days or such further period as the Registrar may allow.*

*(2) The Registrar shall, as soon as possible after receipt of any comments furnished to him or her as contemplated in subsection (1), either resolve the matter or submit the complaint together with such comments, if any, to the Council, and the Council shall thereupon take all such steps as it may deem necessary to resolve the complaint.*

It is advisable that complainants require to see a copy of the scheme's response prior to the registrar ruling. It should also be noted that the CMS may take “any steps necessary” to resolve the complaint. This CMS has, for example, established a Clinical Committee that advises on the clinical merits of a particular complaint. The complaint should therefore be formulated in a manner that would allow both the lawyers at the CMS, as well as the Clinical Committee, to evaluate the case.

Any party aggrieved with a Registrar Ruling can appeal in terms of section 49:

### 49. Appeal against decision of Registrar.

*(1) Any person who is aggrieved by any decision of the Registrar under a power conferred or a duty imposed upon him or her by or under this Act, excluding a decision that has been made with the concurrence of the Council, may within 30 days after the date on which such decision was given, appeal against such decision to the Council and the Council may make such order on the appeal as it may deem just.*

*(2) The operation of any decision which is the subject of an appeal under subsection (1) shall be suspended pending the decision of the Council on such appeal.*

*(3) The Registrar or any other person who lodges an appeal in terms of subsection (1) may in person or through a representative appear before the Council and tender evidence or submit any argument or explanation to the Council in support of the decision which is the subject of the appeal.*<sup>(9)</sup>

The above means that there are only 30 (calendar) days after a ruling on an initial complaint to appeal the ruling. No condonation is possible, as is the case with the 30 day period under section 47. It also makes it clear that the ruling is suspended, i.e. should not be implemented until the appeal ruling but has to do so within 30 days after the date of the ruling. This appeal is heard at a hearing convened by the CMS of its Appeal Committee, which is

done in person. The Appeal Committee is chaired by a senior legal practitioner, external to the CMS. Both the scheme and the patient/provider, as well as the CMS, have the opportunity to address the Appeal Committee. Although not necessary, it is highly recommended that, at this stage, expert legal- and clinical support be obtained for the patients and/or provider.

If a party is not satisfied with the outcome at the Appeal Committee level, they can approach the CMS's Appeal Board for a so-called section 50 appeal within 60 days of the Appeal Committee ruling.<sup>(9)</sup> At this stage the appeal submission takes the form of affidavits. It is therefore imperative that legal advice and assistance be obtained. It should also be noted that, unlike section 49, no suspensive provision exists in section 50. This means that the ruling of the Appeal Committee is not suspended pending the Appeal Board ruling.

## CONCLUSION

Understanding the legal framework and the rights afforded to patients by medical scheme legislation is a critical component of acting as the advocate of a patient. Both doctors and patients are often caught off guard if they are informed that the medical scheme does not cover what would be appropriate treatment for a patient.

Being able to identify what the real concern of the scheme is (e.g. cost or the potential of floodgates being opened) would provide insight into how to respond. Understanding how the legal framework caters for both the patient's needs, as well as that of the scheme to contain costs is important. Arguing within this legal framework, whilst understanding how medical schemes are different to other insurance mechanisms, should assist practitioners in achieving the best possible outcomes for their patients.

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Visit the HeFFSA website ([www.hefssa.org](http://www.hefssa.org)) and complete the questionnaire based on this article for Ethics points.

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