Mr. Daniel Lehutjo
Acting Registrar: Council for Medical Schemes
c/o Clinical Unit
Council for Medical Schemes

By email: pmbreview@medicalschemes.com
By fax: 086 242 4821

SAMED submission to Circular 83/2016

Prescribed Minimum Benefits Review

27 January 2017

Dear Mr Lehutjo,

Submission on Prescribed Minimum Benefit Review: Proposed construct and work plans

The South African Medical Device Industry Association (SAMED) thanks the Council for Medical Schemes (CMS) for the opportunity provided through Circular 83 of 2016 and Circular 1 f 2017, to participate in the Prescribed Minimum Benefits (PMB) Review process. We applaud your team in the effort to develop a more inclusive healthcare system and look forward to engaging with you throughout this process.

This extremely important review process will have an impact on not only the manner in which schemes are required to fund PMBs, but could well have an adverse impact on those people within the population that are currently being treated for a specific PMB condition, which may become unfunded and therefore untreated due to this review.

SAMED represents the interests of the Medical Devices and In Vitro Diagnostics (IVD) industries in South Africa. These industries are critical in ensure healthcare delivery through providing Medical Devices and IVDs, for not only the treatment of PMB conditions, but also for the diagnosis of such conditions.

SAMED makes this submission with full reservation of our- and our members' rights and with objection to the short timelines for this submission, taking into account the period the circular was issued at a time when most businesses were winding down, with most staff only in the office in the second week of January 2017. This has left limited time for SAMED to engage its membership on this issue, and to properly ventilate its views. These views are important to the review process and the impact that such process will have on not only the industry, but also the

patients and facilities that the industry services.

SAMED understands, from the circular and the document “Prescribed Minimum Benefit Review: Proposed construct and work plans”, dated 2 December 2016, that a significant change, beyond a mere review, of the PMBs is on the cards.

SAMED have also noted that a 100%-alignment with what is proposed in the NHI White Paper (December 2015) as the NHI benefit package, is envisaged. The nature and purpose of a medical scheme, as a private voluntary funding system is markedly different to that of a national, or even a social health insurance scheme. A fundamental change in the motivation for medical scheme cover would necessitate also a fundamental change in the legislative framework, as well as the funding and benefit models of schemes. Such fundamental changes cannot occur in isolation and without considering the other elements of social security systems, e.g. funding, subsidization, etc.

The benefit package re-design should follow principle discussions on the nature of medical scheme cover, its role in a future healthcare system, and vis a vis the NHI, the sources of funding and systems of delivery.

These discussions can also not be had without considering the not implemented aspects of the medical schemes regime, such as the absence of risk equalization and mandatory cover. SAMED submits that, whatever the package, without these elements, the medical scheme system would face similar challenges as it currently does. If some other pertinent matters, such as regularly updated coding, are addressed, some of the concerns relating to the PMBs may also be addressed.

It does seem that what the review aims to address, is not that of gaps or concerns with the PMBs, but a massive transformation of the whole essence of the medical schemes system. SAMED would not in principle object to a re-design of the PMB process, but such cannot be done without considering the various contexts as outlined above.

It must be noted that the Proposed construct and work plans document refers to a period of consultation that has preceded the publication of these documents. We also note that Circular 1 of 2017 again re-states stakeholder engagement in 2016, however to the best of SAMED’s knowledge none of its members, or itself, has been engaged and we believe the same holds true for our customers.

Current Challenges

The current PMB list (i.e. what is contained therein and the descriptions of treatment) is extremely outdated. The law requires that the list needs to be reviewed every two years, and the responsible regulatory bodies have failed to uphold this. This has resulted in the PMB list falling further and further behind in terms of treatment regimes and its responsiveness to South African healthcare needs. Any new knowledge on conditions and treatments, as well as treatments with medical devices should be taken into account. In the past, only treatments with medicines were possible (the issue of "treatable cancers" being an example).

CMS must factor in various studies including any ultimate findings concerning the current Health Market Inquiry (HMI) by the Competition Commission into the cost of private health sector, prior to making any final review. The HMI plans to release no less than four very important reports that may impact the work of the CMS and the National Department of Health on the PMBs. One of these reports will deal exclusively as to whether the PMBs are indeed a cost driver, and its impact on the market. Indications from the HMI submissions and the reports issued in December are that the PMBs are indeed not a cost driver, and that above-inflation increases in healthcare expenditure is, for the largest part, explainable by factors that are not related to provider exploitation, for example. It does seem that the Review aims to address the PMBs in terms of the belief that it is a cost-driver.

Insofar as incorrect or inaccurate coding may contribute to the cost of the PMBs, such an issue could be resolved through the implementation of an accepted, transparent, national coding system. This review indicates that this problem is avoidable with the implementation of the "baskets of care" package. However, whatever the content / benefits of the "baskets of care" package are, a record must be kept of the services and goods used in the diagnosis, treatment and care of a patient. The procedural and other professional codes as well as their descriptors must be updated and further defined to make provision for various eventualities. Such an update will ensure that Healthcare Practitioners code correctly and accurately. It will also avoid the issue where professionals and others are required to use incorrect codes to ensure cover for services and goods, where services and/or goods have no code.

It is alleged in the Proposed construct and work plans document published by the CMS on 2 December 2016, that there is currently an "uncontrolled introduction of new healthcare technology, which may result in cost increases without an improvement in the quality of care". No evidence is provided for this statement. Given the fact that there is a current lack of data at an industry level on the role of medical devices and health technology in the PMBs, the statement is perplexing. Until 2013 the CMS required breakdowns of hospitalization costs that included these

categories, but has not done so subsequently. Its lifting out of “medical technology” unfortunately did not address medical devices, but rather medical technologists, as a profession.

The introduction of new technology is very much, and quite effectively controlled both in terms of introduction, upgrades or newer models, as well as in terms of price (not cost-effectiveness) by funders and hospital groups. The absence of a legally-endorsed system, that embodies criteria such as those set for the selection of medicines (formularies – regulation 15I) or caps (regulation 15G), or a proper system of preferred suppliers (as opposed to preferred providers) in terms of regulation 8, makes suppliers vulnerable to systems that are not based on evidence-based medicine, outcomes and/or cost-effectiveness. Both funders and hospital groups have implemented various processes in order to curtail and curb the introduction and/or expansion of most technologies. The control, introduction and pricing of new and existing technologies is therefore set by the funders and the hospitals themselves, without any legislative criteria to protect patient interests and outcomes.

The current guidelines and protocols, which are being relied upon by funders to fund PMB conditions are outdated. Although the definition of evidence-based medicine (-healthcare), as entrenched in the law should find application when PMB benefits are designed and outlined, this is unfortunately not the case. SAMED proposes an introduction of clear PMB treatment guidelines, based on clinical studies or the best available evidence (as defined in the regulations), done by the CMS in consultation with key stakeholders including clinical associations and industry, as the minimum standard of meaningful care. Provision must also be made for non-responders, and the current practice of the PMB algorithms only referring to treatment as medicine, and should be expanded to include all forms of treatment. These guidelines should also include exactly what would constitute a PMB condition with clear definitions and what would be the relevant codes that would cover that condition. These guidelines and protocols should ensure that the correct clinically appropriate and cost-effective (as opposed to cheap) treatment is provided the first time around to the members to ensure no wasted costs on incorrect treatment or treatment that is not based on evidence-based medicine.

Proposed solutions to the current PMB’s

It is imperative that any new healthcare package must take into account those members of the population that are covered by medical schemes. An expansion or limitation of benefits will have an effect on existing rights and legitimate expectations of persons covered by medical schemes. The fact that certain types of cover will no longer be available under the amended short- and long-term insurance regimes, must also be considered. If the idea is, through affordability measures, i.e. by drumming down the PMBs significantly, to attract more members of lower income into medical schemes, SAMED strongly recommends research is done in this regard, as

such benefit lowering will not only affect the lower options, but all options. There should be certainty that the consumers, at which these lower cost options would be aimed, are indeed interested in these options.

Furthermore, the NHI White Paper states that medical schemes would only provide top-up cover to the NHI and not cover in parallel thereto. Therefore, what is being proposed appears to be against the NHI policy at this stage. SAMED would not oppose a system whereby medical schemes are able to also deliver NHI cover, which system would be aligned with the initial SHI – social health insurance principles. If that, however, is the objective, it must be stated clearly.

The impact of a reduced or different PMB package on the state sector as a possible provider, or as a mandated or appointed Designated Service Provider, and the impact on non-medical scheme members, must also be considered. Before the implementation of the NHI, what type of burden will this have on state funded facilities, which would then be required to treat these patients. Whilst it is appreciated that moving towards a system where primary healthcare is provided for an entire population, the interim measures must not detrimentally affect the people that the new system seeks to protect.

One manner in which to treat PMB conditions is to consider various Centers of Excellence for the more prevalent and high cost PMB conditions. These centers can be a vehicle to drive down costs due to the specific set of skills and experience provided, which will result in better outcomes. These centers will need to be peer-reviewed and the outcomes data of each condition assessed and captured. These centers should be easily accessible in all provinces in South Africa and should not be purely based on contractual price considerations. The Healthcare Professionals at these centers would therefore diagnose and treat these conditions, quicker and in a more effective manner, thus saving costs as surgeries will not need to be redone or revised.

A new coding project should be given priority in order to rectify the current inadequacies, omissions or outdated codes. This coding project could be given priority through a Public Private Partnership where the Council for Medical Schemes, the National Department of Health, industry and associations are consulted to ensure updated and appropriate coding is in place in light of the e-Health initiative of NHI.

To avoid fragmentation and movement of members between funders and thus driving costs up, SAMED suggests that there should in future be transference of e-files between funders with due consideration for consumer protection and confidentiality. This to be an interim measure until the full platform of patient e-files is in place.

Tel: +27 11 704 2440 | Fax: +27 086 407 4765 | email: info@samed.org.za
PO Box 651761, Benmore, 2010, South Africa | Hammets Crossing Office Park, No. 2 Selbourne Avenue , Randburg

A clear and transparent, democratic system of setting algorithms, protocols and guidelines together with an update of these is required. The CMS and National Department of Health should mandate and work together with various clinical associations and academic institutions to roll this project out. There should further be a specific body nominated in order to continuously update these guidelines and protocols. The guidelines should inform the PMB descriptions (the difference between the PMB definition project and this review not being clear) and all associated diagnostic and care provision codes.

A further solution to the current burden of the cost of PMB conditions is to have a closer collaboration between public and private sector in upskilling Healthcare Professionals to increases efficiencies and patient out-comes and thus drive costs down.

Proposed Healthcare package

The list of what would be contained in the PMB package is by no means clear as to what would be covered and to what depth it would be covered. The use of words such as “curative” are problematic, as many of the conditions that creates South Africa’s serious burden of disease are not curable. SAMED proposes that the healthcare package must include Non-Communicable Diseases (many of which it does, through the Chronic Disease List (CDL), currently). There should also be a mechanism where alternative reimbursement models and Designated Service Providers (DSPs) can be included, properly framed in the law so as to prevent patients from sub-quality, ineffective and/or meaningless care. Incorporating cost effectiveness (based on evidence-based medicine) and reintroducing the Risk Equalization Fund (REF) as well as mandatory medical scheme membership by the employees earning above the tax threshold will make the PMB package more sustainable.

Any proposed future healthcare system should make provision for health technology evaluation criteria specific for devices. In tertiary level institutions, device integration and utilisation needs to be fast tracked to allow for improved review of technology. There should also be a requirement to ensure that tertiary institutions are on the forefront of technology and skills. This also necessitates a procurement system at tertiary level that differs from that at secondary and primary care level. Systematic reviews and Randomized Control Trials (RCTs) are not always suitable for medical devices and various other considerations need to be employed, for example: new technology benefits, registries, cohort studies etc. Stakeholder engagement is of the utmost importance.

Any new proposed healthcare system must take into account health outcomes and the quality of life of the patient. Any medical intervention or treatment plan must make the necessary provision for a better quality of life for the patient being treated. The aim should always be optimal patient

Tel: +27 11 704 2440 | Fax: +27 086 407 4765 | email: info@samed.org.za
PO Box 651761, Benmore, 2010, South Africa | Hammets Crossing Office Park, No. 2 Selbourne Avenue , Randburg
www.samed.org.za

outcome and not purely the saving of costs.

SAMED is happy to engage the CMS on any of the above aspects and is of the view that stakeholder involvement in this process is of paramount importance together with the active involvement of health economists in ensuring that any new model proposed is in fact less of a cost burden. We also humbly request that due consideration for HMI releases be granted and the CMS consider a urgent workshop to clarify Circular 83 of 2016 and follow-up circular. This will facilitate robust engagement prior to any commentary from stakeholders.

We humbly request that you afford us the opportunity to meet with you on a separate occasion to discuss our submission more substantially.

Yours faithfully,

T Vogt

Tanya Vogt
SAMED Executive Officer

.