CIRCULAR

Reference:	Performance of Health Technology Assessments
Contact person:	Ms Hannelie Cornelius – Acting General Manager: Accreditation
Tel:	012 431 0406
E-mail:	h.cornelius@medicalschemes.co.za
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Circular 25 of 2022: Performance of HTAs by Managed Care Organisations and/or medical schemes – Statutory provisions and proposed way forward

The Council for Medical Schemes (CMS) published Circular 57 of 2020 requesting the industry, in particular, Managed Care Organisations (MCOs) performing Health Technology Assessments (HTAs), to provide information on, among other things, the rationale for performing HTAs, the methodologies used and the basis for the calculation and charging of fees, etc.

This was following complaints from pharmaceutical suppliers regarding MCOs allegedly performing HTAs on behalf of medical schemes and some even charging a fee for the service for having a particular medication, device, etc., listed on its protocols or formularies.

Several MCOs and one industry body responded to the call for information. In summary, the respondents all agreed on the following:

a. That HTAs are vital for clinical, financial risk management and funding decisions;

b. That an independent body comprising of members with relevant technical skills and expertise should be established in South Africa to perform HTAs objectively and efficiently; and

c. Most funders and MCOs perform HTAs but do not charge suppliers or manufacturers for the said services or to include medicines and other health technologies in their protocols and/or formularies. The costs associated with performing these are recovered by MCOs mainly through the managed care fees charged to client medical schemes, save for a few exceptions where the costs are recovered from the pharmaceutical or other suppliers in terms of the fee charged.

CMS' position on the performance of HTAs and the recovery of the costs

1. The CMS acknowledges that the performance of HTAs in respect of new medicines, devices, etc., is a critical part of the clinical and financial risk management processes of MCOs and/or medical schemes to provide for cost-effective and clinically appropriate products to be included in the protocols and/or formularies.

2. Whilst CMS is mindful of the fact that performing HTAs successfully requires expert technical skills and often significant financial resources; it is concerned that the practice by MCOs of charging suppliers or pharmaceutical entities for conducting HTA does not find expression in the law given the following:

   a) The Regulations of the Medical Schemes Act (131 of 1998) (MSA) define *a 'managed health care organisation' as a person who has contracted with a medical scheme in terms of regulation 15A to provide a managed health care service;*

   b) The same regulations further define '*managed health care' as a 'clinical and financial risk assessment and management of health care, with the view to facilitating appropriateness and cost-effectiveness of relevant health care services within the constraints of what is affordable, through the use of rules-based and clinical management-based programmes';*

   c) What is, therefore, evident from the above definitions is that managed health care services should be conducted under the conclusion of a contract between the medical scheme and the managed care organisation, respectively. Put differently, the governance of managed health services should be informed by the terms of a contract concluded between the medical scheme and the managed health care organisation.

   d) The abovementioned contract should be informed by the prescripts of the MSA and its regulations – more specifically, Regulation 15 of the Act.

   e) Regulation 15 defines managed health care as *clinical and financial risk assessment,* which is conducted to facilitate *the appropriateness and cost-effectiveness of health care, taking into cognisance affordability through rules-based and clinical management-based programmes*. It is common cause that the risk and clinical assessment conducted under the auspices of 'managed health care' culminate in the development of protocols and formularies which assist medical schemes' funding decisions.

   f) While it is accurate that the Medical Schemes Act regulations are silent on how the protocols and formularies are to be developed, the regulations outline the principles of appropriateness, cost-effectiveness, affordability and evidence-based as the basis to inform the managed care.

   g) When one analyses the ''reviews'' undertaken by the MCOs in this context, it is evident that the said reviews constitute managed health care to the extent that the reviews comply with the principles of managed health care as defined in Regulation 15 of the Medical Schemes Act no 131 of 1998 in that they adopt a formal technique designed to evaluate clinical necessity, appropriateness, efficacy and efficiency with the view to develop protocols and formularies for the benefit of medical schemes.

   h) Furthermore, CMS is opined that the reading of the provisions of the Regulation 15 prescripts should be read against the backdrop of section 7 of the Act, which provision bestows the Council the obligation to protect the interest of beneficiaries of medical schemes at all times.

   i) It would therefore be remiss of the CMS to abstain from engaging on issues about the conduct of MCOs since the practice adopted by MCOs could potentially affect the members of schemes,

Proposed way forward

1. The CMS will engage with the National Department of Health (NDoH) and the South African Health Products Regulatory Authority (SAPHRA) to discuss the potential of establishing an independent body charged with performing HTAs for all new medicines, technology, etc., which will then be available to all relevant stakeholders in both the public and private health sectors.

2. In the meantime, whilst the establishment of an independent national body to perform HTAs is under discussion/development, the private industry is called upon under the guidance of the CMS and, in terms of providing oversight over the process, to centralise the current HTA capacity that exists in the industry and form a voluntary, independent HTA task team/working group to conduct HTAs for the private medical scheme industry.

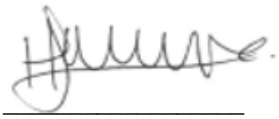
3. Such a task team/working group should comprise of members with the required expertise and skills to be able to conduct HTAs robustly and transparently.

4. Due consideration will be given to the costs involved and possible recovery thereof.

5. CMS will play a leading role in determining the criteria to be used for the performance of HTAs in an independent and objective manner and in identifying/determining appropriate criteria to be applied by all MCOs or medical schemes in determining which products are considered and/or included on formularies.

6. MCOs, medical schemes and relevant industry stakeholders are invited to provide detailed comments on the CMS position and proposed way forward. Comments may be emailed to Ms Hannelie Cornelius at h.cornelius@medicalschemes.co.za by 20 May 2022.

Yours sincerely,



Ms Hannelie Cornelius
Acting General Manager: Accreditation
Council for Medical Schemes