COUNCIL FOR MEDICAL SCHEMES

MANAGED HEALTH CARE POLICY DOCUMENT
Version 1 (August 2003)

1. Introduction

1.1. A new set of regulations governing managed health care activities in South Africa took effect on 1 January 2003, by way of amendment to the general regulations[1] made in terms of the Medical Schemes Act, 1998 (hereinafter referred to as "the regulations" and "the Act" respectively).

1.2. These changes also impact on further amendments to the regulations relating to the content and delivery of the prescribed minimum benefits, published simultaneously with the managed care amendments but which take effect on 1 January 2004.

1.3. Implementation of these regulations falls within the regulatory jurisdiction of the Council for Medical Schemes ("the Council"). Given the fact that there has not previously been an overarching regulatory framework for managed health care, the Council has considered it appropriate to issue this policy document describing its intended approach to various issues relating to the implementation and interpretation of the relevant regulations.

1.4. In so doing, we seek to promote sufficient legal certainty to allow for appropriate managed health care activities to develop without undue restraint. To the extent that application of these regulations gives rise to judicial precedent or other legally binding determinations, this document will be amended accordingly. The document will also be incrementally developed as new issues are drawn to our attention which warrant inclusion.

1.5. Accordingly, this policy document will be identified by reference to versions, with the first issue being referred to as Version 1. The latest version of this document will always be available on the Council website: www.medicalschemes.com.

1.6. If there are issues which readers would specifically like to see addressed in future versions of this document, suggestions should be sent to Stephen Harrison, Head: Research and Monitoring (email: s.harrison@medicalschemes.com).

[1] GNR. 1360 GG 24007 4/11/2002

2. Regulatory framework

2.1. Chapter 5 of the regulations is reproduced as Annexure A, but should always be read in the context of the regulations as a whole.

2.2. The structure of these regulations is as follows:

2.2.1. Regulation 15 defines certain terms which are used in the Chapter, including amongst others "managed health care," "evidence-based medicine" and "capitation agreement."

2.2.2. Regulation 15A determines certain prerequisites for managed health care arrangements, including the need for agreements between managed health care organizations and medical schemes to be in writing and, as of 1 January 2004, for managed health care organizations to be accredited by the Council.

2.2.3. Regulation 15B sets out procedural requirements in respect of the granting of accreditation to managed health care organizations by the Council, as well as defining the parameters of information requirements of the Council for accreditation purposes.

2.2.4. Regulation 15C sets out the grounds and procedure for suspension and withdrawal of accreditation.

2.2.5. Regulation 15D sets out certain material standards for the conduct of managed care business, relating amongst others to utilization review protocols, clinical review criteria, professional oversight and transparency of programmes and procedures.

2.2.6. Regulation 15E deals with the relationship between medical schemes or managed health care organizations and participating health care providers, including certain basic contractual requirements and some limitations on preferred provider arrangements.

2.2.7. Regulation 15F sets out certain requirements for capitation agreements entered into by medical schemes.

2.2.8. Regulations 15G to 15I set out certain prerequisites for the application of limitations on disease coverage, protocols and formularies respectively.

2.2.9. Regulation 15J contains certain general provisions relating to contracts between medical schemes and managed health care organizations, perverse incentivisation of health care providers, confidentiality, and complaints procedures.

3. Points of Departure

3.1. The Council's first point of departure in developing an approach to implementation of these regulations is that appropriate managed health care is a worthwhile and indeed necessary feature of private health care funding in South Africa.

3.1.1. In the period immediately prior to implementation of the Act, medical schemes were able to apply traditional risk-rating practices to *avoid* or *exclude* risk to their schemes.

3.1.2. Traditional insurance underwriting practices are now significantly limited by the Act, which requires, for example, open enrolment and community rating.

3.1.3. The appropriate response from medical schemes is to shift their business model from one which focuses on avoidance and exclusion of risk to one which is focused on effective *management* of risk.

3.1.4. In essence, medical schemes need to integrate sound financial management with sound clinical management in order to ensure that interventions are clinically appropriate and cost-effective.

3.1.5. Medical schemes and their membership will benefit most if the best health outcomes are achieved through evidence-based and affordable interventions. If managed health care interventions can achieve this, then they are a useful adjunct to the business of medical schemes.

3.1.6. In particular, the Council recognizes the potential significant advantage of managed health care to the extent that it can:

3.1.6.1. promote the use of most cost-effective health care delivery mechanisms, and thereby achieve cost reduction;

3.1.6.2. align the financial incentives of providers and financiers to reduce perverse incentives for unnecessary care;

3.1.6.3. entrench mechanisms to maintain or improve quality of health care;

3.1.6.4. encourage the development of standardized treatment approaches;

3.1.6.5. support members in gaining access to the most appropriate treatment interventions; and

3.1.6.6. promote an integrated and holistic approach to managing the health care needs of patients.

3.2. Secondly, the Council recognizes that since the mid-1990's a number of models of managed health care have emerged in South Africa, some of which are reflected in Diagram 1 below. In implementing the managed health care regulations, the Council recognizes the need for further innovation to allow for the emergence of uniquely South African models of managed health care, provided that such innovation is lawful and does not compromise the interests of consumers of health care.

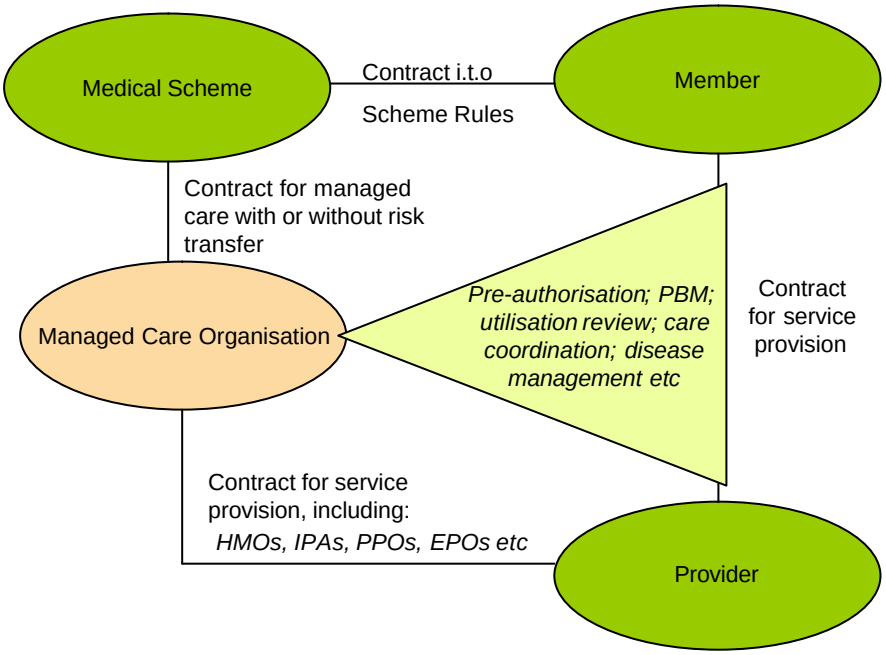

Diagram 1

3.3. Thirdly, while the value that may be added to health care through managed health care interventions is recognised, the Council is acutely aware that this is an area susceptible to abuse and that consumers are in special need of protection in a managed health care environment. Particular concerns of the Council in this regard include, amongst others:

3.3.1. the use of individual medical information for managed health care purposes exposes consumers to particular risks of breaches of confidentiality;

3.3.2. in the absence of excellent data collection and management, the effects of managed health care in terms of improving quality of care through better health outcomes may be impossible to ascertain;

3.3.3. perverse incentives may be created for providers to maximize profit through under-servicing;

3.3.4. managed health care may result in obstacles which decrease access to appropriate care through: hidden limitations on benefits, unreasonable restrictions on choice of provider, or complex and bureaucratic procedural requirements;

3.3.5. managed health care interventions may result in increased expenditure of medical schemes, if the administrative expenditure on implementing managed health care does not result in corresponding cost benefits through more cost effective provision of care; and

3.3.6. contractual arrangements may be used by unscrupulous stakeholders to inappropriately remove reserves of medical schemes.

3.4. Fourthly, although the Council for Medical Schemes bears responsibility for overall administration of the managed health care regulations, the onus for providing sound governance in relation to implementation of managed health care interventions (and thereby maximizing their advantages and minimizing their risks) remains with the trustees of the particular medical schemes employing such techniques or contracting with managed care organizations to employ such techniques.

4. Specific Regulatory Issues

This section of the document is intended to provide clarity on the Council's intended approach to various issues relating to the implementation and interpretation of the relevant regulations.

4.1. Accreditation

4.1.1. The effect of regulation 15A(1)(b) is that, with effect from 1 January 2004, a managed health care organization will be unable to contract with medical schemes unless that organisation is accredited with the Council.

4.1.2. Accreditation is a process by which the Council will review a managed health care organization's operations to ensure that the organization:

4.1.2.1. is fit and proper to provide managed health care services;

4.1.2.2. has the necessary resources, systems, skills and capacity to render the managed health care services which it wishes to provide; and

4.1.2.3. is financially sound.

4.1.3. The Council has issued a discussion document providing more information on the accreditation process, as well as the set of standards against which it intends to assess managed health care organizations to satisfy itself of the required

competencies, as set out in the previous paragraph. A copy of this discussion document is attached as Annexure B.

4.1.4. Various applications for accreditation were received by the Council prior to the most recent amendments to the regulations, but have not been processed. Given the fact that the information in these applications may now be out of date, and that the information provided is in general not adequate for an assessment in terms of the amended regulations, these applicants will be requested to submit revised applications in terms of the new accreditation requirements. If these applicants have already paid the required application fees, they will not have to make any additional payment.

4.1.5. In terms of regulation 31(j), the fee payable for an application for accreditation as a managed health care organization is R10 000,00.

4.2. Confidentiality of medical information

4.2.1. In applying the managed health care regulations, the Council will prioritise enforcement and monitoring of compliance with the confidentiality provisions of these regulations, most specifically regulations 15J(2)(b) and (c).

4.2.2. This will also be a key feature of any accreditation decisions (see standard 4.2 in Annexure B).

4.2.3. The Council is currently reviewing the adequacy of confidentiality protections in the Act, regulations and other laws, and will make recommendations to the Minister of Health to strengthen these protections if they are considered inadequate in any respect.

4.3. Effect of non-compliance with Regulation 15A(2)

4.3.1. Regulation 15 A (2) provides that "To the extent that managed health care undertaken by the medical scheme itself or by a managed health care organisation results in a limitation on the rights or entitlements of beneficiaries, the medical scheme must furnish the Registrar with a document clearly stating such limitations, which document must be resubmitted to the Registrar within 30 days of any amendment to such limitations taking effect, including the relevant amendments."

4.3.2. This regulation effectively requires filing of the relevant document with the Registrar's office, and does not require approval of such document by the Registrar (as is the case, for example, with the rules of medical schemes).

4.3.3. The Registrar will accordingly not routinely scrutinize the documents to ascertain whether or not the managed health care limitations contained therein are lawful. However, in the event that a complaint is lodged with the Registrar

alleging unlawful application of managed health care interventions, the Registrar will have reference to the relevant filed document to make a determination on the lawfulness or otherwise of the stated limitations.

4.3.4. The Registrar will also make documents filed in terms of this regulation accessible to persons requesting such information in terms of the Promotion of Access to Information Act, and who are entitled to obtain access to such documents in terms of that Act.

4.3.5. Council takes the view that failure of a medical scheme to file the relevant document in terms of this regulation will not affect the validity of the relevant managed health care interventions, but would attract administrative penalties in terms of section 66(3) of the Act, and would constitute a criminal offence in terms of section 66(1) of the Act.

4.4. Therapeutic switching

4.4.1. Questions have been raised regarding whether it would be appropriate for medical schemes to make payment conditional upon therapeutic switching of medicines (as opposed to generic substitution). The Council declines at this point to make a general policy determination on the permissibility of therapeutic switching.

4.4.2. Nevertheless, the Council will address this issue on a case-by-case basis, considering the merits in each situation. In the event of a complaint being lodged against a medical scheme in relation to this practice, the Council will be also be guided by policy and advice provided by the Medicines Control Council.

4.5. Application of managed health care to prescribed minimum benefits ("PMBs")

4.5.1. Regulation 8 clearly authorises the use of managed health care interventions in the context of PMBs. The relevant subregulations are as follows:

"(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 preauthorization, 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[2]."

4.5.2. Where medical schemes apply managed health care interventions to PMBs, such interventions are not only subject to the provisions of subregulations 8(5) and 8(6) and section 29(1)(p) of the Act, but those managed health care interventions must also comply in all respects with all the requirements of Chapter 5 of the regulations.

4.5.3. The reference in subregulation 8(4) to section 29(1)(p) of the Act has the effect that, where a benefit is obtained in a public hospital and that benefit constitutes a minimum benefit as prescribed and is equivalent to entitlements of public sector patients, managed health care interventions applied by the medical scheme may not give rise to any further limitations on those services.

4.5.4. The question has been asked whether, as part of the managed health care interventions applied by a medical scheme, protocols may be applied which limit the number of consultations which may be made annually by a beneficiary to a medical practitioner for purposes of particular prescribed minimum benefits. This is particularly pertinent in respect of the chronic disease list. Such protocols would be permissible provided that they comply with the all the relevant provisions of Chapter 5 of the regulations, including inter alia regulation 15H, which requires that:

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.

4.5.5. Clearly, if limitations on number of consultations as contemplated in paragraph 4.5.4 are applied, such limitations would not be considered evidence-based unless they were determined individually per condition, and they would have to apply to individual beneficiaries as opposed to family limits. For example, it would not be considered evidence-based for a protocol to be developed which

[2] As defined in the regulations, **'emergency medical condition'** means the sudden and, at the time, unexpected onset of a health condition that requires immediate medical or surgical treatment, where failure to provide medical or surgical treatment would result in serious impairment to bodily functions or serious dysfunction of a bodily organ or part, or would place the person's life in serious jeopardy.

stated that a maximum of 4 consultations to general practitioners annually would apply to an individual for all chronic conditions (irrespective of the nature of chronic conditions and/or the number of chronic conditions suffered by an individual).

4.5.6. The applicability of regulation 15H(c) needs emphasis, to the effect that if a protocol limitation on number of visits would cause harm to a beneficiary, appropriate exceptions would need to be made without penalty to the beneficiary.

4.5.7. The question has also been asked, particularly in the context of the chronic disease list in the PMBs, whether it would be permissible for a medical scheme to insist on a specialist, as opposed to a general practitioner, confirming diagnosis of the condition prior to treatment of the condition being authorized by the medical scheme. As a general rule, a limitation to this effect would be considered unreasonable. However, there are a limited number of conditions where specialist confirmation of such a diagnosis would be considered clinically appropriate. In those instances, a protocol to this effect would be considered permissible, provided that the medical scheme is able to provide adequate justification for this condition based upon evidence-based medicine, taking into account considerations of cost-effectiveness and affordability.

4.5.8. It is important to note that, whereas managed health care should be directed toward ensuring that the health care needs of beneficiaries of medical schemes are managed appropriately and cost-effectively, managed health care interventions may not detract from the essential content of prescribed minimum benefits. Most particularly, beneficiaries of medical schemes may not be denied continued access to prescribed minimum benefits should they not meet lifestyle modification or treatment regimen compliance requirements imposed by medical schemes.

4.6. Imposition of copayments in respect of PMBs

4.6.1. Regulation 8(5) permits a medical scheme to impose a copayment on a member 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.

4.6.2. The other circumstance in which a medical scheme is permitted to impose a copayment on a member in respect of a PMB is when that medical scheme designates a service provider for the delivery of PMBs, and that member or his or her dependant *voluntarily* obtains such services from a provider other than the designated service provider.[3]

[3] The circumstances in which a beneficiary is regarded as having involuntarily obtained a service from a provider other than a designated service provider are set out in regulation 8(3).

4.6.3. In both these circumstances in which copayments may be imposed, the following principles will be applied by the Council for Medical Schemes:

4.6.3.1. The relevant co-payment must be approved in the rules of the scheme. If the co-payment is unreasonably prejudicial to members' interests, Council will not approve the co-payments. As a guideline, given the intention of the legislation, it would seem reasonable for the quantum of the co-payment to relate to the difference between actual cost incurred and the cost that would have been incurred had the designated service provider been used (or in the case of drugs, the difference between the cost of the drug and the reference price of the formulary drug). A 100% co-payment would amount to an exclusion, and would be considered completely unreasonable.

4.6.3.2. Co-payments cannot be paid out of medical savings accounts, as this would amount to a contravention of regulation 10(6), which prohibits the cost of prescribed minimum benefits, as defined, from being paid from MSAs. The definition of "prescribed minimum benefit" does not differentiate between co-payments and other costs of PMB treatment.

5. Related regulatory issues

Various other issues have been raised by stakeholders in the context of discussions on the implementation of the managed health care regulations, but which extend more broadly than policy relating to managed health care. Given the fact that these issues nevertheless impact on managed health care, they are addressed here for purposes of completeness.

5.1. ICD 10

5.1.1. It is indisputable that benefits provided by medical schemes can be most appropriately managed if those medical schemes have access to sound diagnostic data. Accordingly, the Council supports the need for industry-wide implementation of ICD 10, as well as the importance of entrenching this standard through legislation.

5.1.2. The Council nevertheless acknowledges practical difficulties with mandating implementation of ICD 10 in 2004 (such as training requirements, system changes, adequacy of confidentiality protections, public sector readiness, oversight responsibility and monitoring capacity).

5.1.3. The Council will accordingly be recommending to the Department of Health that the use of ICD 10 should be mandated with effect from 1 January 2005, subject to appropriate exceptions being made.

5.1.4. In the meantime, the Council will be recommending that NHISSA (the National Health Information System of South Africa), located within the Department of Health, should spearhead the move toward ensuring public and private health sector readiness to implement this coding system.

5.2. Utilisation of benefit limitations in respect of PMBs

5.2.1. It has already been stated that medical savings accounts ("MSAs") may under no circumstances be used to pay for the costs of PMBs. The additional question has been raised of whether or not medical scheme payments in respect of a PMB can be deducted from a member's specific benefit limits (within the risk pool - not MSAs).

5.2.2. From the perspectives of benefit design, equitable access to benefits and financial administration of schemes, there are significant advantages to separating the benefit structure and potentially the risk pool for PMBs from other benefits. The Council will continue to engage in discussion around these issues in the context of the financial soundness taskteam and other deliberations on forms of unfair discrimination in the medical schemes environment.

5.2.3. For the moment, the benefit design in the rules of medical schemes will continue to be evaluated on a case-by-case basis to determine if, by design or otherwise, they have the effect of unfairly discriminating against certain categories of members.

6. Conclusion

This document is brought to you in the interests of maximum transparency in regulatory approach. In conclusion, we would like to reiterate that if you have any comments or would like to see additional issues addressed in future versions of this document, please avail yourself of the opportunity to do so.

Annexure A

Chapter 5 of the Regulations: Provision of Managed Health Care

Definitions

15. For the purposes of this Chapter –

'capitation agreement' means an arrangement entered into between a medical scheme and a person whereby the medical scheme pays to such person a pre-negotiated fixed fee in return for the delivery or arrangement for the delivery of specified benefits to some or all of the members of the medical scheme;

'evidence-based medicine' means 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;

'managed health care' means clinical and financial risk assessment and management of health care, with a view to facilitating appropriateness and cost-effectiveness of relevant health services within the constraints of what is affordable, through the use of rules-based and clinical management-based programmes;

'managed health care organisation' means a person who has contracted with a medical scheme in terms of regulation 15A to provide a managed health care service;

'participating health care provider' means a health care provider who, by means of a contract directly between that provider and a medical scheme in terms of regulation 15A, or pursuant to an arrangement with a managed health care organisation which has contracted with a medical scheme in terms of regulation 15A, undertakes to provide a relevant health service to the beneficiaries of the medical scheme concerned;

'protocol' means a set of guidelines in relation to the optimal sequence of diagnostic testing and treatments for specific conditions and includes, but is not limited to, clinical practice guidelines, standard treatment guidelines, disease management guidelines, treatment algorithms and clinical pathways;

'rules-based and clinical management-based programmes' means 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.

Prerequisites for managed health care arrangements

15A. (1) If a medical scheme provides benefits to its beneficiaries by means of a managed health care arrangement with another person –

(a) the terms of that arrangement must be clearly set out in a written contract between the parties;

(b) with effect from 1 January 2004, such arrangement must be with a person who has been granted accreditation as a managed health care organisation by the Council; and

(c) such arrangement must not absolve a medical scheme from its responsibility towards its members if any other party to the arrangement is in default with regard to the provision of any service in terms of such arrangement.

(2) To the extent that managed health care undertaken by the medical scheme itself or by a managed health care organisation results in a limitation on the rights or entitlements of beneficiaries, the medical scheme must furnish the Registrar with a document clearly stating such limitations, which document must be resubmitted to the Registrar within 30 days of any amendment to such limitations taking effect, including the relevant amendments.

(3) Limitations referred to in subregulation (2) include, but are not limited to: restrictions on coverage of disease states, protocol requirements, and formulary inclusions or exclusions.

Accreditation of managed health care organisations

15B. (1) Any person desiring to be accredited as a managed health care organisation must apply in writing to the Council.

(2) An application for accreditation as a managed health care organisation must be accompanied by –

(a) the full name and curriculum vitae of the person who is the head of the managed health care organisation's business;

(b) the home and business address and telephone numbers of the person referred to in paragraph (a);

(c) a copy of the proposed managed health care agreement or agreements between the managed health care organisation and the medical scheme or medical schemes concerned; and

(d) such information as the Council may deem necessary to satisfy it that such person –

i. is fit and proper to provide managed health care services;

ii. has the necessary resources, systems, skills and capacity to render the managed health care services which it wishes to provide; and

iii. is financially sound.

(3) In considering an application for accreditation in terms of this regulation, the Council may take into consideration any other information regarding the applicant, derived from whatever source, if such information is disclosed to the applicant and she or he is given a reasonable opportunity to respond thereto.

(4) The Council must, after consideration of an application –

(a) if satisfied that an applicant meets the criteria listed in items (i),(ii) and (iii) of subregulation (2)*(d)*, grant the application subject to any conditions that it may deem necessary; or

(b) if not so satisfied, refuse the application and provide reasons to the applicant for such refusal.

(5) If accreditation is granted by the Council in terms of subregulation (4)*(a)*, it shall be granted for twenty-four months, and shall be accompanied by a certificate from the

Registrar clearly specifying the expiry date of the accreditation and any conditions imposed by the Council in terms of subregulation (4)(a).

(6) The Council may at any time after the issue of a certificate of accreditation, on application by a managed health care organisation or on own initiative add, withdraw or amend any condition or restriction in respect of the accreditation, after having given the relevant managed health care organisation a reasonable opportunity to make submissions on the proposed addition, withdrawal or amendment and having considered those submissions, if the Council is satisfied that any such addition, withdrawal or amendment is justified and will not unfairly prejudice the interests of the clients of the managed health care organisation, and must in every such case issue an appropriately amended certificate to the managed health care organisation.

(7) A person wishing to renew accreditation as a managed health care organisation shall apply to the Council for such renewal in such format as the Council may from time to time determine, provided that –

(a) such application for renewal shall be made at least three months prior to the date of expiry of the accreditation; and

(b) such person shall furnish the Council with any information that the Council may require.

(8) The provisions of subregulations (4) to (6) shall apply *mutatis mutandis* to an application for renewal of accreditation in terms of subregulation (7).

Suspension or withdrawal of accreditation

15C. (1) The Council may, subject to subregulation (2), at any time suspend or withdraw any accreditation granted in terms of regulation 15B if the Council is satisfied on the basis of available information, that the relevant managed health care organisation –

(a) no longer meets the criteria contemplated in regulation 15B(2)*(d)*;

(b) did not, when applying for accreditation, make a full disclosure of all relevant information to the Council, or furnished false or misleading information;

(c) has, since the granting of such accreditation, contravened or failed to comply with any provision of this Act;

(d) has, since the granting of such accreditation, conducted his or her business in a manner that is seriously prejudicial to clients or the public interest;

(e) is financially unsound; or

(f) is disqualified from providing managed health care services in terms of any law.

(2) *(a)* Before suspending or withdrawing any accreditation, the Council must inform the managed health care organisation concerned of –

(i) the intention to suspend or withdraw the accreditation and the grounds therefor;

(ii) in the case of suspension, the intended period therefor; and

(iii) any terms attached to the suspension or withdrawal, including such measures as the Council may determine for the protection of the interests of the clients of the managed health care organisation,

and must give the managed health care organisation a reasonable opportunity to make a submission in response thereto.

(b) The Council must consider any such response, and may thereafter decide to withdraw or suspend or not to withdraw or suspend the accreditation, and must notify the managed health care organisation of the decision.

(c) Where the accreditation is suspended or withdrawn, the Council must make known the terms of the suspension or withdrawal or subsequent lifting thereof, by means of any appropriate public media announcement.

(3) During the period that the accreditation of a managed health care organisation has been suspended, such person may not apply for renewal of the accreditation or reapply for accreditation.

(4) On withdrawal of the accreditation of a person as a managed health care organisation, the Council may determine a reasonable period within which such person may not reapply for accreditation as a managed health care organisation, taking into account the nature of the circumstances giving rise to such withdrawal.

Standards for managed health care

15D. If any managed health care is undertaken by the medical scheme itself or by a managed health care organisation, the medical scheme must ensure that:

(a) a written protocol is in place (which forms part of any contract with a managed health care organisation) that describes all utilisation review activities, including a description of the following:

(i) procedures to evaluate the clinical necessity, appropriateness, efficiency and affordability of relevant health services, and to intervene where necessary, as well as the methods to inform beneficiaries and health care providers acting on their behalf, as well as the medical scheme trustees, of the outcome of these procedures;

(ii) data sources and clinical review criteria used in decision-making;

(iii) the process for conducting appeals of any decision which may adversely affect the entitlements of a beneficiary in terms of the rules of the medical scheme concerned;

(iv) mechanisms to ensure consistent application of clinical review criteria and compatible decisions;

(v) data collection processes and analytical methods used in assessing utilisation and price of health care services;

(vi) provisions for ensuring confidentiality of clinical and proprietary information;

(vii) the organisational structure (e.g. ethics committee, managed health care review committees, quality assurance or other committee) that periodically assesses managed health care activities and reports to the medical scheme; and

(viii) the staff position functionally responsible for day-to-day management of the relevant managed health care programmes;

(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;

(e) health care providers, any beneficiary of the relevant medical scheme or any member of the public are provided on demand with a document setting out –

(i) a clear and comprehensive description of the managed health care programmes and procedures; and

(ii) the procedures and timing limitations for appeal against utilisation review decisions adversely affecting the rights or entitlements of a beneficiary; and

(iii) any limitations on rights or entitlements of beneficiaries, including but not limited to restrictions on coverage of disease states; protocol requirements and formulary inclusions or exclusions.

Provision of health services

15E. (1) If managed health care entails an agreement between the medical scheme or a managed health care organisation, on the one hand, and one or more participating health care providers, on the other –

(a) the medical scheme is not absolved from its responsibility towards its members if any other party is in default to provide any service in terms of such contract;

(b) no beneficiary may be held liable by the managed health care organisation or any participating health care provider for any sums owed in terms of the agreement;

(c) a participating health care provider may not be forbidden in any manner from informing patients of the care they require, including various treatment options, and whether in the health care provider's view, such care is consistent with medical necessity and medical appropriateness;

(d) such agreement with a participating health care provider, may not be terminated as a result of a participating health care provider –

(i) expressing disagreement with a decision to deny or limit benefits to a beneficiary; or

(ii) assisting the beneficiary to seek reconsideration of any such decision;

(e) if the medical scheme or the managed health care organisation, as the case may be, proposes to terminate such an agreement with a participating health care provider, the notice of termination must include the reasons for the proposed termination.

(2) A managed health care organisation or a medical scheme, as the case may be, may place limits on the number or categories of health care providers with whom it may contract to provide relevant health services, provided that –

(a) there is no unfair discrimination against providers on the basis of one or more arbitrary grounds, including race, religion, gender, marital status, age, ethnic or social origin or sexual orientation; and

(b) selection of participating health care providers is based upon a clearly defined and reasonable policy which furthers the objectives of affordability, cost-effectiveness, quality of care and member access to health services.

Capitation agreements

15F. A medical scheme shall not enter into a capitation agreement, unless –

(a) the agreement is in the interests of the members of the medical scheme;

(b) the agreement embodies a genuine transfer of risk from the medical scheme to the managed health care organisation;

(c) the capitated payment is reasonably commensurate with the extent of the risk transfer.

Limitation on disease coverage

15G. If managed health care entails limiting coverage of specific diseases –

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

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

Protocols

15H. 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.

Formularies

15I. 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.

General provisions

15J. (1) Any managed health care contract, contemplated in Regulation 15A, must require either party to give at least 90 days notice before terminating the contract, except in cases of material breach of the provisions of the contract, or where the availability or quality of health care rendered to beneficiaries of a medical scheme is likely to be compromised by the continuation of the contract.

(2) Notwithstanding anything to the contrary in these regulations –

(a) a medical scheme and a managed health care organisation may not use any incentive that directly or indirectly compensates or rewards any person for ordering, providing, recommending or approving relevant health services that are medically inappropriate;

(b) any information pertaining to the diagnosis, treatment or health of any beneficiary of a medical scheme must be treated as confidential;

(c) subject to the provisions of any other legislation, a medical scheme is entitled to access any treatment record held by a managed health care organisation or health care provider and other information pertaining to the diagnosis, treatment and health status of the beneficiary in terms of a contract entered into pursuant to regulation 15A, but such information may not be disclosed to any other person without the express consent of the beneficiary;

(d) where provision is made by a managed care provider for complaints or appeals procedures or mechanisms, such provision shall in no way impact upon the entitlement of a beneficiary to –

(i) complain to, or lodge a dispute with, his or her medical scheme;

(ii) lodge a complaint with Council; or

(iii) take any other legal action to which he or she would ordinarily be entitled.

Annexure B

Consultation Document:
Accreditation of Managed Care Organisations
Dated July 2003

Comments on this document are invited to reach the Council no later than 11 August 2003, for the attention of:

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1. Introduction:

1.1. Managed care, within the South African context, is a term used to refer to a diverse range of healthcare organisational strategies aimed at controlling cost, improving access and assuring higher levels of quality of care provided to those covered by medical schemes.

1.2. The Regulations promulgated in terms of the Medical Schemes Act, 1998, Act No 131 of 1998, hereinafter referred to as the "Act" and the "Regulations" define managed care as *"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 rule-based and clinical management-based programmes"*

1.3. The regulations also define a managed care organisation as *"a person who has contracted with a medical scheme in terms of regulation 15A to provide a managed care health care service"*. The regulations further require any person entering into a managed care arrangement with a medical scheme to be accredited by the Council for Medical Schemes, hereinafter referred to as the "Council".

1.4. The Council envisions managed health care service provision and financing which is optimally coordinated to ensure affordability, accessibility and quality of care, and which is focused on meeting physical, emotional, social, and spiritual needs of individuals while respecting their privacy and personal integrity.

1.5. Accreditation is considered as a process by which the Council will review a managed care organization's operations to ensure that the organization is conducting business in a manner consistent with defined standards. The accreditation process consists of:

(a) A review of the application, contract(s), organizational structure, policies and procedures;
(b) An onsite visit to the applicant organization to determine that it has in fact, the required skills, infrastructure and systems capable of providing managed care services in terms of the contract(s) entered into with medical schemes; and
(c) A reporting system that enables the Council to monitor the performance of the organisation and eventually, the overall impact of managed care on the South African medical schemes industry.

1.6. The foreseeable required core competencies for a managed care organization include the following:

(a) Promote and expand access to appropriate, efficient and effective health care services;
(b) Provide competent and customer focused services;
(c) Comply with all relevant acts and regulations;
(d) Accommodate expanded accountability to the relevant stakeholders;
(e) Create a working environment that is conducive for staff development, motivation and innovation;
(f) Manage information and ensure confidentiality;
(g) Continue to learn and improve; and
(h) adequately addresses relevant ethical and clinical issues.

1.7. The Council may request such information as it may deem necessary to satisfy it that the managed care organisation:

(a) Is fit and proper to provide managed health care services;
(b) Has the necessary resources, systems, skills and capacity to render the managed health care services which it wishes to provide; and
(c) Is financially sound.

1.8. It is also important to mention that this document is a living document which may be amended as and when occasioned.

1.9. All managed care organisations should give due consideration to the application of the "code of corporate practices and conduct" as defined in the "King II Report", in so far as the principles are applicable. Stakeholders

interacting with such organisations are encouraged to monitor the application by these organisations of the principles set out in the code. Organisations are required to measure the principles set out in the code with other statutes and regulations and other authoritative directives regulating their conduct and operation with a view to applying not only the most applicable requirements, but also to seek to adhere to the best available practice that may be relevant to the organisation in its particular circumstances.

Accreditation should, however not be equated with an endorsement by the Council of the products or services offered by those organizations who have successfully applied for accreditation. The assurance provided to stakeholders does not relieve trustees of medical schemes from their fiduciary duty to exercise their powers to the benefit of the scheme, whilst displaying reasonable care and skills in this regard.

2. The Accreditation Process:

2.1. The application:

Managed care organisations that wish to apply for accreditation should apply in writing to the Council for Medical Schemes. A set of documents including the application form, the accreditation standards, the measurement criteria and a list of required documents will be sent to the applicants. The applicant should then return the completed application form and accompanied by all the required documents.

Upon the submission of the complete application, the Accreditation Unit at the Council for Medical Schemes will evaluate the content allocating weighted scores to each and every standard. The following assessment is possible:

- **Compliant**: which means all criteria are met
- **Partially Compliant:** which means the applicant met most of the criteria stipulated under the standard.
- **Non-Compliant:** which means the applicant did not meet the stipulated criteria.
- **Not Applicable:** which means the standard or part of the criteria are not relevant to the kind of services provided by the applicant.

Based on the aggregated weighted score, the managed health care organisation would receive written feedback from the Council for Medical Schemes stating one of the following accreditation awards:

- Accreditation, without specific conditions;
- Accreditation subject to certain conditions; or
- Refusal of accreditation.

2.2. The on-site visit:

On-site visits to verify information in applications for accreditation will take place at the discretion of the Registrar.

2.3. The reporting system:

Each and every managed care contract should incorporate a clearly stipulated service level agreement with a defined reporting mechanism that enables the medical scheme to monitor the performance of the organisation. As a condition of accreditation, managed care organisations may be obliged to comply with all the reporting requirements as determined by the Registrar from time to time, and this may include inter alia documentation pertaining to:

(a) continued financial soundness;
(b) underwriting results in terms of the contract;
(c) the quality of the contracted services provided.

Non-compliance with these reporting requirements might lead to suspension or withdrawal of accreditation.

3. The Accreditation Standards:

Section 1 – General Compliance

Objectives

In terms of the Medical Schemes Act and Regulations framed thereunder, managed care organisations are required to apply for accreditation and meet specific criteria. This section is intended to promote adherence to these criteria and the application of best practices.

Standard 1.1

The current or proposed managed care organisation operates as a bona fide provider of managed care services, is based in South Africa, and has applied for accreditation in terms of regulation 15(B)(2) of the Act.

Measurement:

1.1.1 An application for accreditation has been made and is accompanied by all required supported documentation.

Standard 1.2

The managed care organisation has in place, signed agreements with medical schemes in compliance with Chapter 5 of the Regulations or, in the case of a newly established organization, has pro-forma agreements which adhere to the relevant regulations...

Measurement:

1.2.1 The agreements exist for all medical schemes for whom managed care services are provided.
1.2.2 The agreement confirms the scope and duties of the organisation for each specific scheme
1.2.3 The agreement confirms that the organisation will provide the services in full compliance with the Act, the regulations and the rules of the scheme.
1.2.4 The agreement contains full details of fees payable by the medical scheme including the basis of determination and payment.
1.2.5 The agreement provides for measures to ensure confidentiality of beneficiary information.
1.2.6 Provision is made in the agreement for the duration thereof.

1.2.7 The agreement provides for a formal mechanism which deals with complaints/ disputes and appeals against the organisation which may be lodged with the scheme concerned and does not prevent the complainant from lodging complaints/ disputes and appeals to the Council;

1.2.8 Provision is made in the agreement that if managed care services are sub-contracted by the organisation to another provider, such other provider must be duly accredited as a managed care organization by the Council.

1.2.9 The agreement contains service levels for compliance by the organisation and penalties for failure to comply.

Standard 1.3

Capitation agreements (where applicable) entered into comply with Regulation 15F

Measurement:

1.3.1 The agreement constitutes a bona fide transfer of risk from the medical scheme to the managed care organization.

1.3.2 The agreement provides for a capitation based payment which is reasonably commensurate with the extent of the risk transfer.

1.3.3 The nature of the agreement serves the interest of the members of medical scheme concerned.

Standard 1.4

The managed care organization does not do the business of a medical scheme or an insurer

Measurement:

A sworn declaration that, outside of the contracts with the relevant medical schemes, the organization does not undertake liability in return for a contribution or premium –

(a) to make provision for the obtaining of any relevant health service;

(b) to grant assistance in defraying expenditure incurred in connection with the rendering of any relevant health service; and

(c) where applicable, to render a relevant health service, either by the medical scheme itself, or by any supplier or group of suppliers of a relevant health service or by any person, in association with or in terms of an agreement with a medical scheme.

Standard 1.5

The managed care organisation is in a financially sound position.

Measurement:

1.5.1 An auditor has been appointed to examine the accounting records and annual financial statements of the managed care organisation in accordance with the South African Auditing Standards and in compliance with South African Statements of Generally Accepted Accounting Practice ("GAAP").

1.5.2 The financial assessment clearly confirms that the managed care organisation's business:

(a) Has assets which are at least sufficient to meet current liabilities;

(b) Provides for all liabilities; and

(c) Is conducted in a manner to ensure that the business is at all times in a position to meet its liabilities.

Standard 1.6

The organisation has in place, policies and procedures to ensure that health care providers and beneficiaries of the relevant medical scheme or any interested party has reasonable access (on demand) to documents setting out:

(a) A clear and comprehensive description of the managed health care programmes and procedures; and

(b) The procedures and timing limitations for appeal against utilisation review decisions adversely affecting the rights or entitlements of a beneficiary, and

(c) Any limitations on rights or entitlements of beneficiaries, including but not limited to restrictions on coverage of disease states, protocol requirements and formulary inclusions or exclusions.

Measurement:

Submission of a policy document which confirms compliance with the above mentioned criteria.

Standard 1.7

The organisation has a mechanism to identify, measure and manage potential business and other related risks.

Measurement:

Submission of documented proof outlining the organisation's risk management programme.

Standard 1.8

The organisation has in place, an ethics committee, which deals with the following:

1.8.1 All ethical issues pertaining to the organisation's functions.

1.8.2 Ensures that staff members are trained on ethical issues which are relevant to their job description.

1.8.3 Ensures that the organisation's reimbursement, bonuses, or incentives system to staff or health care providers/ suppliers does not compromise member's healthcare, best interests, or quality of care.

Measurement:

Documented proof of composition and terms of reference of the Ethics Committee.

Section 2 – Organisational structure, policies, procedures and system assessment

Objectives

Good business practice requires that the organisation has a detailed process map of its operational functionality and relevant policies and procedures that define operational systems and processes.

Standard 2.1

A detailed business system process map of all operational functions is available.

Measurement:

2.1.1 The applicant is able to provide a process map of its current operational functions

2.1.2 The process evaluation map demonstrates how all operational processes are integrated.

2.1.3 The process evaluation map demonstrates the ability to integrate any outsourced services.

2.1.4 Provision is made by the organisation for reviewing policies and procedures and implementation thereof.

2.1.5 Provision is made by the organisation to integrate administrative functions, quality improvement and where appropriate, the clinical operations.

2.1.6 The applicant is able to provide an up-to-date organogram aligned to its business process map.

Section 3 – Clinical Oversight

Objective:

To promote clinical effectiveness utilising persons with relevant professional qualifications and skills.

Standard 3.1

To the extent that utilization review activities are undertaken by the organization, a written protocol is in place in compliance with regulation 15D(a).

Measurement:

Evidence of the application of such protocol.

Standard 3.2

Documented clinical review criteria are used which comply with regulation 15D(b)

Measurement:

Evidence of the use of such clinical review criteria.

Standard 3.3

Transparent and verifiable criteria for decision-making affecting funding decisions are used and periodically evaluated in compliance with regulation 15D(c).

Measurement:

Evidence of the use and evaluation of the criteria

Standard 3.4

The managed care organisation implements a written policy that verifies the current professional registration of personnel/consultants upon appointment and thereafter no less than annually. The organisation should also implement corrective action in response to adverse change in registration status.

Measurement:

3.4.1 The written policy is available.

3.4.2 Documented proof exists confirming that all the affected employees have valid registrations with the relevant professional body.

Standard 3.5

The managed care organisation, designates senior staff person(s) who has/have:

(a) Appropriate qualifications and skills to perform clinical oversight for the services provided;

(b) Experience in direct patient care; and

(c) Valid registration with a relevant statutory body.

Measurement:

3.5.1 The existence of such a person or persons in the organisation's staff establishment; and

3.5.2 The qualifications and the work experience of the person(s), as mentioned in the attached C.V., meet the job requirements.

Section 4 – Information management and data control:

Objectives:

Information management is viewed as a strategic enabler for achieving the organisation's objectives. Information must be managed in such a way that promotes integrity and protects the interests of schemes and their members and to promote quality and cost reduction.

Standard 4.1

The organisation has in place, an integrated information system to collect, maintain, analyze and retrieve information necessary for organisational management that:

(a) Provides for data integrity, confidentiality and security;

(b) Provides for appropriate plans to manage back-up of business data and a disaster recovery plan;

(c) Includes a plan for storage, maintenance, retrieval and destruction of business data;

(d) Provides potential for information sharing between the organisation, the contracted medical scheme(s) and the Council for Medical Schemes.

Measurement:

The submission of a brief document outlining the organisation's information system that meets the above mentioned criteria.

Standard 4.2

The organisation has in place, clearly defined policies and procedures for dealing with issues of confidentiality and respecting the right to privacy of medical scheme members, in compliance with relevant laws. Such measures should apply to all forms of data collection, maintenance and transfer, including electronic formatting. Furthermore these policies and procedures should cover inter alia:

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(a) Individual access to own information and third party requests for information are dealt with in terms of the Promotion of Access to Information Act, 2000. An individual should have the right to access his or her own health information in terms of this statute;
(b) Ensuring that personally identifiable health information is not disclosed without patient authorization, except in circumstances authorized by law or with the patient's specific and informed consent;
(c) Where financial, ownership or shareholding links exist between a third party and a managed care organisation, confidential- or personal information obtained by such organisation in the course of its business may not be passed on to-, or be used by- or utilized in any manner by such third party institution or organisation for the purpose of conducting their business.
(d) Adoption of an express consent approach which conveys the concept that the individual has agreed to have information about him/herself made available to certain persons or institutions, which also includes the medical scheme.
(e) When disclosing information for research, the necessary controls to protect patient confidentiality should be put in place.
(f) Existing legal rules in terms of consent by minors and persons incapable of consenting to a disclosure have to be abided by.
(g) Effective and punitive remedies for violations of privacy protections, including employee training and -disciplinary measures, appropriate contractual provisions and penalties with any party contracting with a health care role player, etc.

Measurement:

The availability of a document outlining policies and procedures for dealing with issues of confidentiality and respecting the right to privacy of individuals, granting reasonable protection to members in this regard.

Standard 4.3

The organisation ensures confidentiality awareness by staff through regular training and enforcement.

Measurement:

The availability of documented proof of the training programme and the enforcement plan.

Section 5 – Quality Management

Objective:

The Council for Medical Schemes puts great emphasis on ensuring the provision of quality-driven managed care services to the South African medical schemes industry. Through the accreditation process, managed care organisations are afforded the opportunity to demonstrate their commitment to quality services and ongoing self improvement.

Standard 5.1

The organisation has a written well defined quality management programme that:

(a) Is approved and supported (including commitment of the necessary resources) by senior management;

(b) Clearly defines the scope, objectives, structure and activities of the programme;

(c) Provides for the establishment of a quality management committee as a custodian of the programme;

(d) Includes and maintains at least two ongoing quality improvement projects, focusing on consumers and other key quality indicators.

Measurement:

The submission of documentation which clearly outlines the quality management programme including an outline of the aforementioned criteria.

Standard 5.2

The managed care organisation has in place, a quality management committee that:

(a) Is mandated by senior management to oversee the quality management programme.

(b) Meets regularly and maintains minutes of all meetings.

(c) Guides the organisation on quality management priorities and projects.

(d) Monitors and evaluates the progress made towards achieving the quality management programme goals.

Measurement:

Documented proof of the composition and terms of reference of the quality management committee.