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SUBMISSION ON THE DRAFT REGULATIONS RELATING TO THE OBTAINANCE (sic) OF INFORMATION AND PROCESSES OF DETERMINATION AND PUBLICATION OF REFERENCE PRICE LISTS –
No. R. 1214, 1 December 2006. NATIONAL HEALTH ACT, 2003

INTRODUCTION

The AIDS Law Project (ALP) is a section 21 not-for-profit company and a registered law clinic. It seeks to develop, implement and use laws and policies to protect and advance the rights of people living with and affected by HIV/AIDS. In so doing, it aims to ensure a rights-based response to the HIV/AIDS epidemic that it believes is best suited to reducing new HIV infections and minimising the negative social impact of AIDS. The ALP was part of the Centre for Applied Legal Studies (CALS) at the University of the Witwatersrand, Johannesburg from 1993 until 2006. It is now an independent organization that is formally associated with the Wits School of Law.

Fundamental to our work is the Constitution of the Republic of South Africa, 1996 – the rights that it entrenches; the positive and negative obligations that it imposes on the state; and the structures that it recognises and empowers to ensure the realisation of the values upon which our democratic state is based. In respect of the right to have access to health care services, this means government has a duty to take all reasonable steps to

ensure that the best, fairest and most equitable health system possible within available resources is established.

CONTEXT

The ALP welcomes the opportunity to make a submission on the *Draft Regulations Relating to the Obtainance (sic) of Information and Processes of Determination and Publication of Reference Lists* ("draft regulations").

The ALP accepts that there is a need to address inequity in access to private health care services as well as the need to contain and regulate costs in the private sector. For this reason regular and accurate information about health financing, service prices and business practices in the private sector is essential in determining both health policy as well as a fair and reasonable price for services and products. However, if the draft regulations are to give effect to the objective of obtaining such information then we believe that it should be significantly strengthened.

Below we deal with individual sections of the draft regulations that require strengthening. However, there are 4 key aspects that we hope you will take into account in finalising the draft regulations:

- Unfortunately, the draft regulations provide the Director-General (DG) with the *discretion* to obtain information on an annual basis ("may"). However, we believe that given the importance of this process the discretion should be replaced with an *obligation* to obtain information annually ("shall"). This is not only for the purposes of determining the National Reference Price Lists (NRPLs- Section 8)[1] but also for ensuring that our health policy takes into account annual developments in the private sector. A compulsory process is also important because government is under an obligation to ensure that it correctly determines the necessary level of state intervention and regulatory oversight of the private sector. In addition, given advances in medicine and science, an annual review will ensure that information is accurate and up to date.
- As the regulations stand, verification may occur by the DG or by an advisory committee who assists the DG. However the latter is dependent on two things: whether such a

[1] According to the Council for Medical Schemes, the reference lists are not a set of tariffs, instead the prices per service provided:
-serve as a guide against which medical schemes can individually determine benefit levels ;
-serve as a guide against which health service providers can individually determine fees charged to patients; and
-serve as basis for negotiation between individual funders and individual health care providers.

Committee is established by the Minister and whether the DG seeks its advice (because the draft regulations gives him/her a discretion to do so).

- Regrettably, the draft regulations do not create a mechanism for any interested person/organisation to challenge the methodology, calculations and information submitted by the private sector or consultants who act on its behalf (only the DG can – who may or may not seek the assistance of an advisory committee).
- The proposed 'verification system' is very loosely formulated and requires strengthening.

Below we deal with the substantive aspects of the draft regulations.

1. **Section 2**

As discussed above, because the information contemplated in Section 3 will be used to determine the National Reference Price Lists (NRPLs- Section 8) the Director General (DG) of Health should obtain this information on an annual basis. The word "may" should therefore be replaced with "shall".

2. **Section 3**

a. We propose that under (c) "equipment" - information about whether the equipment is leased or owned should be included as this affects both overhead costs as well as price.

b. While the draft regulations deal with the type of information that has to be submitted, the responsible person, association or body that must submit it, and the criteria that has to be met when submitting information, it fails to provide that supporting documentation – where applicable– must accompany such a submission. This is necessary in order for the DG and/or the advisory committee to verify the information submitted. This proposal could also be incorporated under Section 7 (1).

3. **Section 6 (c)**

It is unclear who will agree to the methodology that will be used. Will it be the relevant provider group, association, independent practitioner or DG? For this reason, the regulations should set out the methodology that will be acceptable pursuant to the NHA and the regulations thereto. Alternatively, a mechanism that allows government departments, statutory bodies, consumer bodies and other interested persons to challenge the methodology must be inserted.

4. Section 7 (2):

There are 2 concerns here -

a. First, given the complexity involved in verifying information about the private health sector (price, financing, other) it would make more sense if the DG is always supported by an advisory committee instead of having to pro actively seek such assistance at his/her discretion ("may"). The current NRPLs issued by the Council for Medical Schemes are technical, complex and intensive. Thus far there are over 20 lists that make up the NRPLs. It would therefore be practically impossible for the DG to be an expert on each and every area that the NRPLs cover. Therefore we propose that the DG should not act without the assistance of technical experts on an annual basis - where he/she is not placed in the difficult position of having to verify information by him/herself.

b. Second, the provision is worded in such a way that it appears to exclude any challenge to the correctness and accuracy of the information by civil society organisations or consumer / other bodies. In other words, only the DG can verify if the information is correct (with the assistance of an advisory committee but only if the DG seeks its assistance). This means that bodies / persons who are not part of the advisory committee are precluded from being part of the verification process.

We therefore propose that the verification process should be strengthened and opened to greater input from all stakeholders. This is especially important because in our view Section 91 (2) of the National Health Act, 2003 offers very little assistance and guidance about the skills that the proposed advisory committee must possess under these circumstances, nor does it offer any significant guidance about the appointment process.[2] We are therefore concerned that even the advisory committee could very well exclude significant inputs from other interested parties who are not appointed or selected to be part of the advisory committee.

5. Section 8 (1)

There is no indication in the draft regulations about the criteria that the DG or the advisory committee will use to verify information. It would therefore make more sense to insert details of the methodology and mechanism that will be used to verify information (subject to an annual

[2] In terms of the National Health Act, 2003: the Minister may:
91. (1) ... after consultation with the National Health Council, establish such number of advisory and technical committees as may be necessary to achieve the objects of this Act.
(2) When establishing an advisory or technical committee, the Minister may determine by notice in the *Gazette*-
(a) its composition, functions and working procedure;
(b) in consultation with the Minister of Finance, the terms, conditions, remuneration and allowances applicable to its members; and
(c) any incidental matters relating to that advisory or technical committee.

review). We believe that the regulations should offer guidance to officials in the exercise of their power – failing this, it could be challenged for being vague.[3]

6. Section 8 (2) (b) and (d)

a. (b) There is minimal detail regarding the manner in which information will be verified. For example, a 'reasonable return on investment' is not defined nor explained. This is problematic because what the private sector views as a reasonable return may be very different from what government and consumer bodies regard as a reasonable return.

b. (d) The need for certainty also applies to the broader private sector, including non-medical scheme beneficiaries. In this respect, *certainty* for people who make out of pocket payments and for people who do not belong to a medical scheme but use the private sector is equally essential. We would therefore propose that this section should be broadened to include all users of the private sector.

We trust that our recommendations will be incorporated in the finalisation of the draft regulations. If you have any queries please do not hesitate to contact me on 083 27 999 62.

Sincerely

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Council for Medical Schemes

[3] [3] See for example *Dawood v Minister of Home Affairs; Shalabi v Minister of Home Affairs; Thomas v Minister of Home Affairs 2000 (1) SA 997 (CC).*

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