# JOINT SUBMISSION ON THE DRAFT NATIONAL HEALTH AMENDMENT BILL, 2008

## INTRODUCTION

The National Health Amendment Bill (the Bill) was simultaneously published with the Medicines Amendment Bill on 18 April 2008. Both Bills are some of the most important pieces of health legislation to be proposed in recent years. The Medicines Amendment Bill is the subject of a separate submission that accompanies this one.

We would like to make clear at the outset that we support the need to regulate the private health sector. We therefore do not take issue with the principle of legislation that allows for this. What we take issue with is the hasty drafting of this legislation which leaves this Bill fatally flawed.

A Bill to introduce a mechanism for the regulation of the private sector is critical and overdue. Justifiably, this Bill is aimed at regulating the manner in which the cost and prices of health care services are arrived at in order to limit unreasonable and unsustainable cost escalation through profiteering from private health care. While in and of itself it is not sufficient, it is central to the constitutional project of progressively realising the right of access to health care services. However the Bill will fail to meet this objective.

In this regard we raise the following concerns:

- the lack of consultation in the process of developing the Bill;
- the lack of independence of the proposed regulatory mechanism;
- the delegation of authority; and
- the ambiguities and gaps in the Bill.

The result of the deficiencies in the Bill will be to render it ineffective, and to delay any reasonable regulation of private health services.

Before we address these concerns we set a context for the consideration of the Bill in relation to the Constitution, health policy, and the funding of health care in South Africa.

## THE CONTEXT OF HEALTH CARE IN SOUTH AFRICA

As we know, the health sector in South Africa is made up of an over-resourced private health care sector and an overburdened public health sector. The private sector is the better resourced in terms of finances, infrastructure and human resources. Yet it only serves 14% of the population.

In recognition of the extreme inequity in access to health care services in South Africa the ANC recommended in 1995 that a range of health care reforms should be implemented. The objective was to reach a point where the reasonable access to health care for everyone is provided through a system National Health Insurance that would ensure that all in South Africa have access to essential health care services regardless of ability to pay.

The private sector is an important role player in the provision of health care services. However, two concerns in particular have been identified by the Council for Medical Schemes.[1] The first is that the lack of affordability of medical scheme cover, due to rising costs in the private sector, means that people with a low income cannot afford to be insured. The second is that 'the expanding private health system disproportionately absorbs health resources in the country'.

The deepening inequity of access to health care services can only be addressed through continuing health care reform, including in the private sector. The ostensible purpose of the proposed legislation is to increase the affordability and accessibility of health care services. This is consistent with the state's duty in terms of section 27 of the Constitution.[2] It is also not an unprecedented type of health reform. Other countries that negotiate tariffs with the private sector (whether in a single funder, or multi-funder environment) include Japan, Germany, Belgium and Switzerland. The regulation of aspects of private health is also evident in the transparent pricing system of the pharmaceutical sector that was introduced in terms of the Medicines and Related Substances Act 101 of 1965.

We note the media reports covering the response by the Democratic Alliance (DA) and the private sector. Their reaction is knee-jerk. At root they do not believe that there should be any regulation of private health care at all. The media has reported that the private sector believes that regulation will 'drive hospitals out of business' that it 'is effectively price control', that 'this is a first step to greater state intervention', that the problem is really with public health care and that it will cause health professionals to leave.[3]

While it is true that there are many things that need fixing in our health system, including the public sector, the statements about the effect that regulation will have on the private sector and generally the morale of health professionals amounts to fear-mongering.

Subject to what is contained in this submission regarding the deep flaws in the Bill, an appropriately appointed regulator would increase transparency in the way prices for health services are set in the private sector. It would not fix

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1 Evaluation of Medical Schemes' Cost Increases: Findings and Recommendations, Council for Medical Schemes, March 2008.

2 *Minister of Health and Another NO v New Clicks South Africa (Pty) Ltd and Others (Treatment Action Campaign and Another as Amicus Curiae)* 2006 (2) SA 311 (CC) at para 314, per Chaskalson CJ

3 Financial Mail, 9 May 2008 and 'Private and public health can co-operate' Independent online, 11 May 2008.

prices. The purpose is not to remove profits from hospital groups or providers, but to prevent excessive profiteering. The hospital sector itself made it evident that they cannot be trusted to be fair in the way they generate profits. In 1998 they had agreed to remove the mark-ups on medicines and that in return they could increase hospital tariffs. It emerged however, that in fact they had not removed the mark ups, but hid them in a rebate system.[4] The consumer bore the cost of their profit-making.

The issue of the prices of commodities that are vital to health care is a crucial determinant of the extent to which people, particularly poor people, have access to health care services and the government's ability to progressively realize this right.

Pricing is not just an issue in relation to medicines. Unjustifiably high prices for medical services and technologies in private hospitals drive up the cost of health care for the insured population and limit the numbers who can afford insurance. This leaves more people dependent on the public sector reducing quality and capacity there. It is therefore a legal duty of the government to reasonably regulate all the drivers of high prices in recognition of the fact that health is not an ordinary commodity over which consumers can exercise ordinary choices.

This principle has been recognized by the Constitutional Court in *New Clicks* where the Court stated that it "unanimously accepted the validity" of a regulatory structure to control the price of medicines.[5] By implication, it will also accept the reasonable regulation of prices in other aspects of health care.

**THE LACK OF CONSULTATION**

The ALP and TAC are not aware of any public consultative process that took place prior to the publication of this Bill. While there may have been consultation with the private sector, to our knowledge such consultation did not include civil society representation.

The Bill was published on 18 April 2008 and requested that submissions be made by 16 May 2008. On 25 April 2008, the ALP wrote to the Department of Health (DoH) to request an extension until 30 May 2008 given the importance and complexity of the subject matter of the Bills (annexure A). On 7 May 2008, the DoH responded to say that an extension would not be possible 'as the Department itself is required to have the Bills tabled in Parliament by not later that 2 June 2008 for the Bills to be considered by Parliament this year. As stated in the said notice, it is the Department's intention that the Bills be considered by Parliament this year.'

While we are aware that there will be further opportunity to make a submission once the Bill is tabled in parliament, we are concerned with the

4 Council for Medical Schemes Report, note 1 above.
5 Note 2 above at paras 12 and 14.

intention of the DoH to rush the process of developing the Bills. In our view the result of inadequate consultation will be to undermine the legitimacy of the legislation.[6] Of especial concern is that there will not be sufficient engagement with the substance of the NHA Bill both in how the regulator is conceptualised and how its powers and duties are captured in the text. Indeed it would not be consistent with the dicta of Justice Sachs that ' [t]he principle of consultation and involvement has become a distinctive part of our national ethos.'[7]

The Constitution embodies a shift from the manner of law-making and governance of the past. It deliberately introduces a requirement of participatory democracy. Relevant to this submission are sections 57, 59 and 195 of the Constitution. These require that participatory democracy must be given effect to by both the legislature and the executive.

Section 195 provides:

(1)Public administration must be governed by democratic values and principles enshrined in the Constitution, including the following principles:

> . . .
> (e) People's needs must be responded to, and the public must be encouraged to participate in policy-making.
> (f) Public administration must be accountable.
> (g) Transparency must be fostered by providing the public with timely, accessible and accurate information.
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> . . .

(2)The above principles apply to –

> (a)administration in every sphere of government;
> (b)organs of state; and
> (c)public enterprises.

In *New Clicks*, the Constitutional Court stressed the importance of participatory democracy and the requirements of the Constitution in this regard.[8] The requirements of participatory democracy apply to the development of legislation before it is tabled in parliament and after.

**THE LACK OF INDEPENDENCE OF THE PROPOSED REGULATOR**

The Bill creates the office of a 'Facilitator' that is meant to facilitate negotiations between relevant stakeholders that are aimed at determining a schedule of fees for health services.

In terms of this Bill, the appointment of the facilitator is an entirely political process. In our view this is fundamentally mistaken. It can undermine

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6 In *New Clicks*, the rushed process of drafting the Regulations contributed to problems of interpretation of the Regulations. The comment period provided was three months. Note 2 above at para 233.

7 *Doctors for Life International v Speaker of the National Assembly and others* 2006 (6) SA 416 (CC) at para 227.

8 Note 2 above at paras 111-112.

negotiations and may result in more deadlocks during negotiations. In an environment with many powerful interests, complex market relations and structure and the need for careful analysis in terms of health economics an independent expert regulator is crucial.

We submit that the Bill should provide strongly for the independence of this regulator, in much the same way as the Independent Communications Authority of South Africa Act 13 of 2000 sought to do. The health regulator should be a juristic person capable of suing and being sued. It must be subject only to the Constitution and the law, must be impartial and perform its function without fear, favour or prejudice. It should be free from any political or commercial interference.

While we do not propose to set out the detail of how such a regulator should be structured in this submission, we believe that given the importance of this body in facilitating the accessibility and affordability of health care and the sensitive and controversial issues that will fall within its ambit, it should possess the following characteristics:

- it must be independent;
- it must be two-tiered (in that there may be an appeal from the regulator to a tribunal, and ultimately the possibility of review by a High Court);
- it must be made up of persons with the relevant expertise, of whom a certain number must be full time appointments;
- its ambit should be broadened to include medicine pricing and the National Health Reference Price List (which currently falls within the responsibility of the Department of Health); and
- its powers and functions must be clearly and comprehensively delineated by legislation.

For this last reason, we submit that the establishment of a health regulator is best done through a separate statute rather than an amendment to the National Health Act.

In addition we are concerned that, the current draft of the Bill politicises the process in the following ways:

**The political appointment of the Facilitator, the Inspector and the Tribunal**

In order for it to be independent, the manner of appointment of key personnel is critical. While the Minister may appoint the members of the regulating body, this should be upon completion of a fair and public process. It should be through a process of nomination that is transparent and open. We would recommend that this is done through parliament in a similar manner to the appointment of members of ICASA. The qualifications of the members of the regulator should be clearly stipulated so that the regulator is made up of appropriately qualified individuals with the expertise to carry out the functions of the regulator. There should be a representative of consumer and patients' interests.

The Bill stipulates that –

- the Minister is to establish a Health Pricing Tribunal and make appointments to this Tribunal 'on the Minister's initiative'. Again, there is no practical reason why this should be left to the 'initiative' of the Minister. An independent process of appointment is necessary for the legitimacy of the Tribunal in an area as fraught as this.
- An Inspector (who conducts searches and seizures) is appointed by the Director-General, and is therefore ultimately accountable to the DoH. We deal with this further below.

**The Minister's rule-making power**

In essence, the Bill leaves too much of the substance of how the regulator is to function to executive determination. In order to preserve its independence overall guidance should be provided in the enabling legislation. Ancillary rules should be left to the regulator itself to determine.

The Bill states that the Minister may make rules relating a range of significant and sensitive issues that require an independent (and an expert) assessment. For example, the Minister may decide the process by which negotiations are initiated, how that process is to be conducted, what information can be called for, rules regarding the participation of any person having an interest in the negotiations, and indeed 'any other matter incidental to the achievement of the objects of this chapter [this Bill]'. In essence, this leaves to the Minister's discretion important matters that ought to be provided for in legislation, or that should be determined by the regulator. We are also concerned about the wide delegation of legislative authority contained in this section and we address this below.

**The Facilitator 'advises the Minister on the compilation and publication of information, reports and statistics about health pricing.'**

It is not stated to what end this advice is given and (except for the schedule of fees) it is unclear whether it is in the Minister's discretion about whether and when to publish such information and the manner of such publication. In fact there should be an explicit responsibility on the Minister to publish information. In order for consumers to make rational choices when they seek health services they should know, for example, what the published fees are and which health providers have opted in to those fees. As a result, even though providers may choose to charge higher prices, the open dissemination of information may act as a disincentive for them to do so. Publishing the schedule and other information in the Government Gazette, however, will not reach the majority of the public.

Finally we would like to clarify that the requirement of independence does not mean that government cannot participate in the proceedings. What it means is that the regulator cannot be subject to undue control by the government or political interference.

## DELEGATION OF AUTHORITY

Our concern with the delegation of authority in this Bill is two-fold: the first relates to the expertise that is necessary to perform certain functions, the second concerns the unfettered discretion that is conferred on officials in certain instances.

With regard to the first concern, and as stated above, we note that there is a wide power of making regulations that is granted to the Minister, some of which requires a degree of expertise that would not necessarily reside in a Minister of Health. There is no guidance provided as to how the Minister is to develop the regulations relating to 'collusive practices' and 'undesirable business practices' for example. One way of dealing with this is for the Minister to make certain regulations 'on the recommendation of' the regulator. If that regulator were constituted in the manner proposed above, then the expertise that resides there should be utilised.

With regard to the second concern, there are at least two instances of unguided discretion:

- the Facilitator is to 'deal with complaints about pricing conduct between medical funders, health providers and suppliers', but there is no guidance as to how to deal with these complaints, whether they should be subject of investigation, who has the power to initiate the investigation, etc.
- The Inspector has detailed powers of search and seizure, but it is not at all clear on whose authority such investigations should be pursued.

In *Dawood v Minister of Home Affairs*[9], the Constitutional Court warned that the legislature must 'take care when legislation is drafted to limit the risk of an unconstitutional exercise of the discretionary power it confers'.

In *Affordable Medicines Trust v Minister of Health*, Ncgobo J held that delegations of power should not be 'so broad or vague that the authority to whom the power is delegated is unable to determine the nature and the scope of the powers conferred.'[10]

Although the exercise of public power by officials is inherently constrained by the Constitution and the law, we would stress again that the particularly sensitive material that will be within the purview of the regulator, and the constitutional duties that it is tasked with carrying out, create a special need for prescribing how delegated authority should be carried out.

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9 2000 (3) SA 936 (CC) at para 48.
10 At para 34.

## VAGUENESS AND GAPS

At various points the Bill is ambiguous or silent on key aspects that raise serious questions of interpretation.

### Medicine pricing

It is unclear whether the Bill is intended to cover drug pricing. It does not specifically exclude medicine pricing from its ambit. On one interpretation it would seem that the term 'services' is broad enough to include medicines. Medicine pricing is certainly relevant to the objects of the Bill, which includes 'improv[ing] transparency in the determination of costs and prices', 'ensur[ing] accountability for the cost of health care' and 'generally, ensur[ing] the affordability of health care'.

To add to this it would seem that this may well have been the intention of the DoH since the Medicine Amendment Bill which accompanies this Bill states in the preamble that one of the purposes of the Bill is to abolish the Pricing Committee that is established in terms of the Medicines Act. However, that Bill does not actually abolish the Pricing Committee.[11]

We submit that it is appropriate and necessary for a health regulator to include within its ambit the issue of drug pricing. As stated above, it is inextricably linked to the affordability of health care and the market of provision of health services in the private sector. It would create a sensible, streamlined and comprehensive approach. It would also bring the Pricing Committee within the set-up of a full time expert regulator (in terms of our proposal).

### The Inspector

Section 89E provides for the office of an Inspector. The only line of accountability would appear to be to the Director-General. There is no connection made between the work of the Inspector and of the Facilitator.

Section 89E(4) sets out the powers of the Inspector to enter premises, search and seize. Yet there is no provision for the basis upon which the Inspector may initiate an investigation, and on whose authority. Similarly, there is simply no provision for what is meant to take place at the end of an investigation. It is not clear to whom the seized material is to be sent, for what purpose and what controls are to be exercised over confidential material. Instead the section on Inspectors sits awkwardly in the middle of the Bill with little rhyme or reason.

We submit that an independent regulator should have the power to appoint the Inspector and initiate investigations in terms of their need to fulfill the objects of the statue and the need to follow-up on complaints by stakeholders and/or members of the public.

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11 See our submission on the Medicines and Related Substances Amendment Bill.

The Inspector should be under an obligation to investigate contraventions of the Act.

**Structural gaps**

As observed above, the legitimacy of this regulatory authority depends on its independence. The structure of the regulator (as proposed above) should therefore be clearly set out in statute.

The duties of the Facilitator are set out in section 89C(2). However there is vagueness in relation to the manner in which the Facilitator is to carry out these duties. The key aspects of these duties is to facilitate negotiations between stakeholders on the pricing of health services, resolving disputes in relation to pricing and dealing with complaints about pricing conduct between funders, health service providers and suppliers. There is no guidance as to how this should be done.

In particular the Facilitator is ill-equipped to resolve disputes or ensure finality in negotiation processes. Especially important in this regard, is the inadequacy of deadlock-breaking mechanisms. If stakeholders do not reach agreement on a schedule of fees, the Facilitator is to 'make recommendations to the stakeholders for consideration on possible schedules of fees.' At the end of the day the Facilitator is powerless. It also has the result of prolonging negotiation proceedings.

Ultimately, it will be up to the Tribunal to make a final determination on the schedule of fees, upon referral by the Facilitator. Again this takes the proceedings through another stage, in which different individuals will have to familiarise themselves with the issues at play, deliberate and make a finding. There is no time constraint imposed on the deliberation of the Tribunal.

Instead, we propose that the bargaining process should be governed by a clear terms of reference, including certain non-negotiables – for example, that there can be no departure from the schedule as far as prescribed minimum benefits are concerned. There should be set time frames for the bargaining process. If a dispute gets referred to a full time decision-making body, there should be clear time frames that govern that process as well. This is important given the need for a degree of certainty and alignment of the budgeting processes of the various role players.

We do not think that this is a context in which it is appropriate to leave the bulk of the manner of conduct of the regulator to the Minister. We note also that the use of the words 'may make rules' is a departure from the usual statutory language of making regulations, that 'the Minister may prescribe Regulations…'. For the sake of removing any ambiguity, and on matters that appropriately fall within the power of the Minister to regulate, we would recommend that the latter language be used.

The purpose of recommending that discretionary powers are limited is not to score points against the current or future Minister. It is simply to limit the possibility of conflict and litigation.

In *Affordable Medicines Trust*, Ngcobo J stated that:

> The law must indicate with reasonable certainty to those who are bound by it what is required of them so that they may regulate their conduct accordingly. The doctrine of vagueness must recognise the role of government to further legitimate social and economic objectives. And should not be used unduly to impede or prevent the furtherance of such objectives. [12]

We believe that this is a situation in which the government should be allowed to pursue the legitimate social and economic objective of enhancing access to affordable health care services. However, a balance must be struck between doing that but allowing for a structure and process that is unambiguous, effective and independent.

**CONCLUSION**

As a result of the deficiencies in the Bill that are outlined in this submission and the fundamental misconception of the role of the regulator, we call for this Bill to be withdrawn and redrafted as a separate statute.

Establishing the regulator as proposed in the Bill will only invite litigation and will hinder the implementation of necessary and urgent reforms. In the meantime the sector will continue to be unregulated, with the ultimate harm being to those who cannot afford to purchase expensive health care. We have already seen this in relation to the Regulations Relating to a Transparent Pricing System for Medicines. It is four years since those regulations were gazetted, and the issue of the dispensing fee is still tied up in litigation.

We urge the DoH to avoid a repeat of that situation by withdrawing the Bill in its current form, addressing comments, engaging meaningfully with the various stakeholders and publishing a substantially revised version of the proposed legislation.

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For further information on this submission, please contact 011 356 4100.

12 At para 108.