Hospital Association South Africa
Advancing Healthcare

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21 July 2014

Hospital Association of South Africa comments on Certificate of Need

Background

Hospital Association of South Africa (HASA) has been informally requested by the Director General to provide input on proposed regulations on the Certificate of Need ("CoN") provisions under the National Health Act, 2003. This commentary is to be read with correspondence directed to the Department of Health by HASA concerning the CoN.

The CoN provisions of the National Health Act 61 of 2003 have been on the statute book for more than ten years now without being implemented. At the time the CoN was first discussed it was highly contested and as a result was not proclaimed. It was therefore a surprise that it was proclaimed in 2014 without any prior warning, consultation or draft regulation.

The health policy context pre-2003 was vastly different to current realities. The current era has been impacted by a plethora of changes to the prevailing legislation –which in turn has impacted healthcare. These include but are not limited to: the Medical Scheme Act 1998; numerous amendment to the Medicines and Related Substances Act in 2002 and 2004; amendments to the Health Professions Act in 2007; Nursing Act in 2005 and 2011; National Health Amendment Bill of 2013,- Office of Heath Standards Compliance; Consumer Protection Act 2008; Protection of Personal Information Act and the Competition Amendment Act which facilitated the commencement of the current Competition Commission private healthcare market inquiry.

Based on this backdrop it is hard to contextualise the reasoning behind the unexpected enactment of the CoN provisions.

As discussed at the meeting with the Director-General on 15 July 2014, HASA is of the firm belief that the abovementioned proclamation has introduced significant uncertainty on the future of healthcare delivery in South Africa and as a result should be withdrawn in order to cure:

- the current legal uncertainty
- the legal effects of the CoN sections on healthcare establishments and the constitutional irregularities currently in existence in respect of the CoN sections.

The retraction will also ensure a considered process of engagement on the proposed regulations with all stakeholders rather than a fast tracked process due to limited time constraints.

We are of the opinion that the considerable regulatory and logistical factors necessary to successfully implement CoN are underestimated given the number of health establishments and the various providers of health services in the country to which this regime applies.

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As a result HASA does not believe it is appropriate to rush input on the regulation and hence this document serves only to inform the Department and Ministry of Health of the current private hospital market dynamics and licensing regime together with the principles of an improved licensing regime for future debate.

The purpose of this document is to therefore address the following topics:

1. The private hospital market, its size, participants and contributions to the South African economy;
2. Who uses private healthcare?
3. Principles of an effective licencing regime;
4. Proposed criteria in making awards in terms of licencing regimes;
5. How to apply a new licensing regime; and
6. International experience of CoN systems.

1. The size of the private hospital market, its participants and its contributions to the South African economy

According to Econex[1] there are 314 hospital facilities operating in SA of which **213** are considered 'Full Hospitals' hospitals or multidisciplinary acute hospitals representing 34,600 beds. There are 101 other or 'non-full' hospitals such as day clinics; rehabilitation; mental health or step down facilities.

Econex[2] estimates that HASA member hospitals had a workforce of 64 000 full-time equivalent employees, and tax contributions of around R5.9 billion in 2010; thus making a substantial direct contribution to the South African economy. When the economic *multiplier* effects of the provision of healthcare services by HASA members are also taken into consideration, HASA members and their value chain sustained production to the value of R110 billion and generated more than R17 billion in government tax revenue during 2010.

For each job offered by HASA member hospitals, 2.4 additional jobs are sustained in the rest of the economy, of which approximately 78% are for individuals from previously disadvantaged backgrounds. In all, approximately 218 000 employment opportunities can be traced back to healthcare activities by HASA member hospitals, generating labour income in excess of R 23 billion during 2010.

HASA members' economy-wide contribution to South Africa's gross domestic product (GDP) amounted to an estimated R52.2 billion in 2010, or 2.2% of the country's GDP. It is

[1] Econex Occasional Note, March 2014: *Market concentration trends in the private healthcare industry*.
[2] Econex Research Note 32, December 2013. *The South African Private Healthcare Sector: Role and Contribution to the economy.*

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estimated that for every R1.00 in sales revenue generated by HASA's members, R1.43 is added to the country's GDP.

In addition, though not quantifiable, the positive impact of private hospitals on labour productivity by improving the health of the labour force in South Africa must not be overlooked. Furthermore, in terms of attracting foreign direct investment, the positive effects of the high standard of medical care offered by private hospitals in South Africa should not be underestimated. Hence, in addition to the economic multiplier effects on output/production and employment, private hospitals also contribute significantly to productivity gains and international investment, which should have a further stimulatory impact on output and economic growth in South Africa.

2. Who uses private healthcare?

In accordance with rights enjoyed by South Africans in the Bill of Rights and those afforded to them expressly by sections 2(c), 8 and 9 of the National Health Act, 2003, South Africans choose to access healthcare in the private sector rather than the public sector – a right also found in various provisions of the Consumer Protection Act No. 68 of 2008. A significant proportion of patients pay for private healthcare through third party payors i.e. medical schemes, insurance, COID, Road Accident Fund etc. Some patients self-fund private healthcare.

In many countries government is also a purchaser of private healthcare services on behalf of public patients. Two South African hospital groups have offshore operations specifically in the United Kingdom and Switzerland where government is a significant purchaser of such private healthcare services.

Demand for private healthcare is not uniform throughout South Africa, but highly variable across provinces as a function of formal employment by those with the means to purchase healthcare services of their choice. Figures 1 and 2 confirm that the demand for public and private hospital services is in fact not uniform throughout the country.

Figure 1 shows the distribution of households' whose normal place of consultation is the private sector by province. In Gauteng and Western Cape there is much more reliance on the private healthcare sector, while in Eastern Cape and Limpopo, there is more reliance on the public sector.

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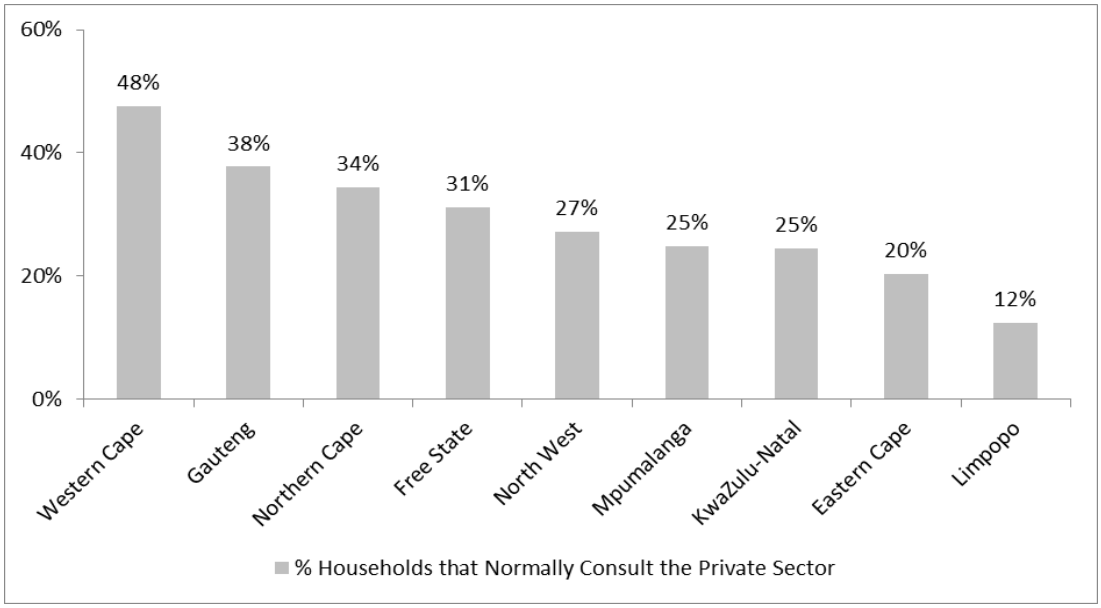
Figure 1: Percentage of households that normally consult the private sector by province



Source: StatsSA, General Household Survey 2012

Figure 2 below shows the percentage of households that would normally consult a private hospital in comparison to a public hospital per province. In Gauteng, 29% of households would normally consult a private hospital compared to Limpopo where only 6% of households would normally consult a private hospital.

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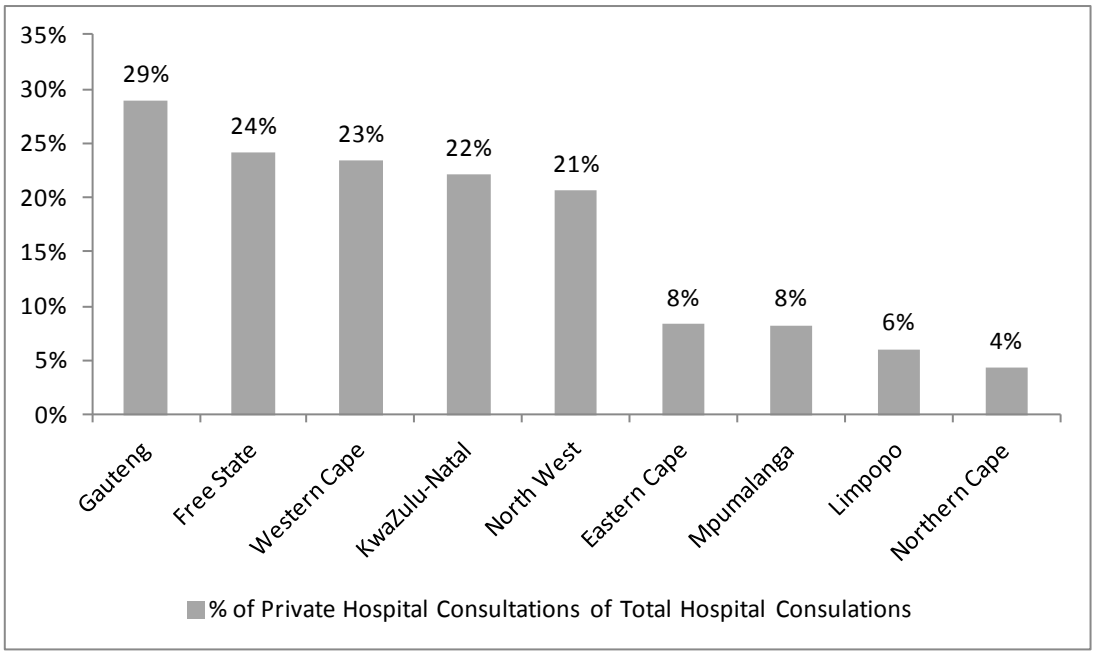
Figure 2: Percentage of households that normally consult private hospitals compared to public hospitals



Source: StatsSA, General Household Survey 2012

Growth in medical scheme coverage tracks formal employment closely. The number of principal members equates to 1 in every 2 formally employed people having medical cover as there are many couples that are formally employed with one 1 principal member in the family. Approximately 8.7million[3] people have private medical cover. Although medical scheme members are also entitled to use the public sector, very few chose to use public hospitals with only 0.3% of medical scheme expenditure in 2012 spent on purchasing care from the public sector[4].

Figure 3 shows that the medical scheme penetration in the formally employed population is higher than 40%.

[3] Council for Medical Schemes, Sep 2013 Quarterly Report
[4] Council for Medical Schemes 2012 Annual report

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Figure 3: Percentage of population on medical scheme and percentage of formal labour force on medical scheme

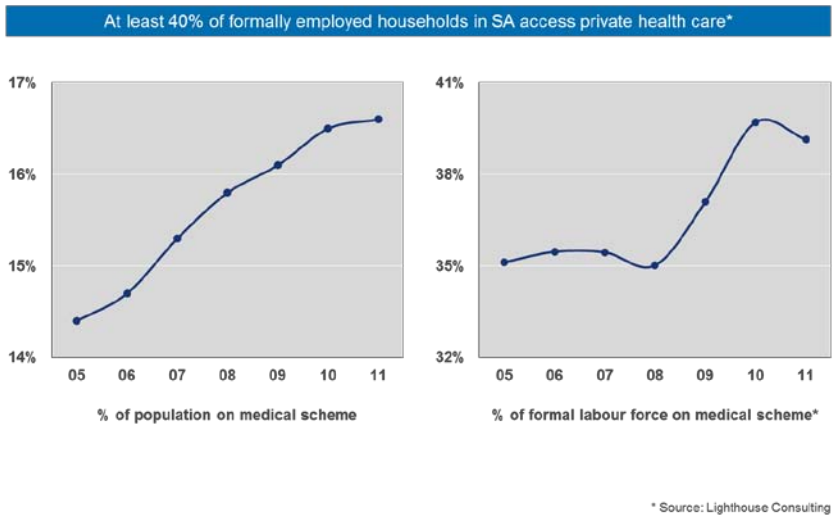

Figure 4 illustrates the proportion of the population on a medical scheme by household income. It is evident that as household income increases, the probability of medical scheme membership increases. Medical scheme membership is very low in lower income households, but rises to around 80% in upper income households.

Figure 4: Proportion of population on a medical scheme by household income

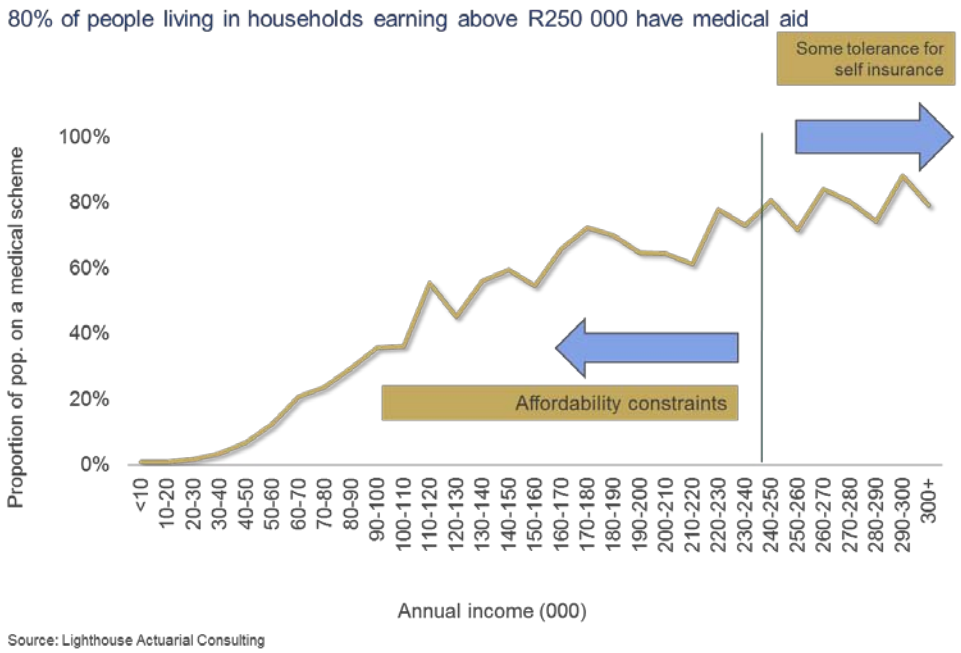

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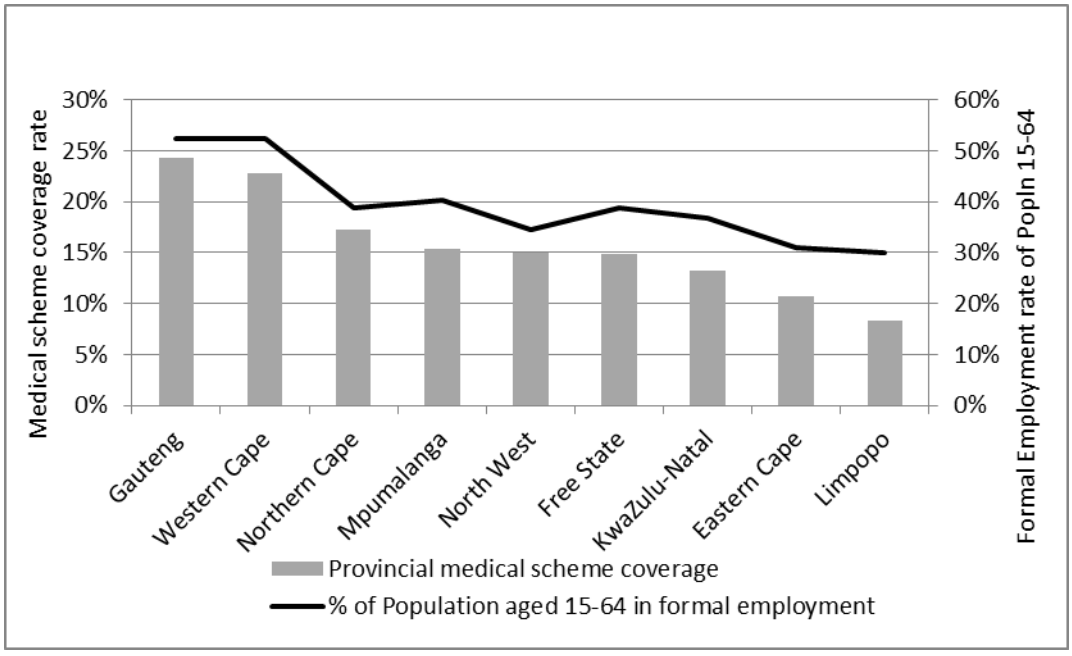
Figure 5 compares the medical scheme coverage rate with the percentage of the population between the ages of 15-64 in formal employment by province. It is clear that the higher the percentage of people in formal employment, the higher the probability of medical scheme coverage. For example, in Gauteng, 52% of the population aged between 15-64 are in formal employment, with a medical scheme coverage rate of 25%. In comparison, in Limpopo, 30% of the population aged between 15-64 are in formal employment with a medical scheme coverage rate of 8%.

Figure 5: Medical Scheme coverage rate by province and percentage of population aged 15- 64 in formal employment by province



Source: CMS annual report 2012, Labour Force Survey 2012

Figure 5 shows that the probability of medical scheme coverage is highly dependent on formal employment rates and resultant income levels in a province. Populations that are formally employed with higher income levels are more likely to have medical scheme coverage and would therefore have a higher demand for private healthcare than lower income and informally employed populations.

The findings above confirm that the private sector in South Africa is no different to private sectors in healthcare systems around the world in that it works to mitigate the demand on the public sector increasing access to healthcare.

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3. Principles of an effective licencing regime

The current hospital licensing regime is governed by Regulations 158 and 187 (R158 and R187) depending on the province. The application of R158 is highly problematic as each province places its own interpretation to it and attends to the administrative procedures and requirements in a different fashion thus creating disparity and uncertainty. In addition, provincial administrators have, on occasion, developed internal policy documents governing the process and adjudication of applications. These documents, which have not been made available for comment, are not freely available in the public domain and are applied inconsistently. All of this operates to create a highly disorganised licensing system. However, such a system and its results are not remedied by the introduction of the CoN. In order for a licensing/certificate of need provision to be rational, reasonable and fair it needs to comply with, at least, the following:

- **National regulation** – To ensure consistency the system should be based on national regulations but be decentralised to the provinces in its application;
- **Independent governance** - The process of licensing should be independently governed and subject to objective criteria that are consistently applied ;
- **Transparent and rational** – the requirements of and evaluation criteria for application should be transparent, rational, objective and clear. The process for acceptance or rejection should be transparent;
- **Adjudication panel -** the parties that adjudicate the application must be appropriately qualified and possess knowledge of the functioning of the private health market.
- **Appeals process** -the process should make allowance for an appeal, at which stage interested and affected parties, who may have commented on the application initially, should be notified of the appeal and again be provided with the opportunity to comment;
- **Consultative process** - the process should be designed to involve all interested and affected parties. Thus, for example, in applications for hospital licenses affected parties given the opportunity to obtain copies of an application and provide comments thereon. The regulations should therefore make provision for a notice and comment procedure in the case of an application for a CoN for a new hospital;
- **Fixed timeframes** -the process, from beginning to end, should be governed by timeframes applicable to the a) applicant b) the Department of Health and c) other parties who may submit comments, to ensure the execution of the decision-making process occurs in an appropriate and reasonable time frame. The timeframes must be written into each step of the process;
- **Cost of application** - the costs of the application should be kept as low as possible in order to encourage competition through new investment; and
- **Promote competition** -the process must encourage competition rather than bar new entrants.

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4. Proposed Criteria making awards in terms of licencing regimes

HASA awaits a proposal from the DOH on a way forward following the engagement between the office of the Director-General and HASA on 15 July 2014. HASA does not believe it is appropriate to engage on the substance of potential regulations at this stage of the engagement.

5. How to apply a new licencing regime

5.1 The licencing regime should only be applicable to:

- Public hospitals; and
- Private hospitals.

5.2 Licensing regime should **not** apply to:

Doctors; multidisciplinary practices; nurses; health professionals as defined by the Health Professions Act; Allied health professionals; Pharmacists; Paramedics, incorporated emergency practices and African Traditional Practitioners for the primary reason that the competency and scope of practice for these professionals are currently governed by their own regulatory framework.

More importantly there is a dire shortage of health professionals in SA. This statistic is deteriorating year on year, impacting the access to healthcare. It is imperative that the DOH health policy is focused on promoting the healthcare as a profession, particularly, medicine as an attractive career option. The current CoN provisions do not contribute to this imperative but rather the associated uncertainty will act as a deterrent to future entrants.

Healthcare professionals are already considered the most over-regulated of the professional groups in SA and the CoN provisions will contribute to making medicine a less attractive career option.

5.3 The licensing regime of hospitals should not apply to medical technology unless compelling and rational reasons can be provided as to why the acquisition of health technology should be subject to a CoN.

5.4 Any replacement or supersession of an existing licensing regime must include a bridge from the current licensing regime to the new licensing regime in a clear fashion that does not unfairly limit the rights existing licensees and operates to secure the rights of existing health establishments – bearing in mind that legislation must be interpreted so as to not deprive a person or a juristic person of his or her or its existing rights – and to ensure the continuity of access to health services pursuant to the applicable provisions of the Bill of Rights. It should be completely unconditional in its operation.

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5.5 Licencing under a new licensing regime should not be subject to a time limitation in the interests of containing healthcare costs as the shorter the duration of the validity of a license, the higher the cost of capital recovery over the shorter period. Shorter licensing periods may also operate to dissuade new entrants and discourage investment in the sector.

6. International experience CoN systems

The necessity and rationale for the provisions on CoN in the National Health Act is questionable for a number of reasons. HASA has reason to believe that the South African CoN concept originated from the United States (US) since no other country in the world appears to have CoN legislation. Other countries, such as Dubai, Switzerland, the United Kingdom, Australia and Italy do have licensing procedures for hospitals but these are not the same in scope or extent as the CoN provisions in South African law and the laws of the various American States.

The US introduced a certificate of need system in the 1970s and HASA believes that it is important to understand the US experience with the certificate of need concept. US experience shows us that:

1. Certificate of need adversely affects access to health care services

The premise that placing regulatory burdens, such as CoN, on the creation of new medical facilities will increase availability of medical services to communities is inherently contradictory. By forcing potential medical professionals to go through an application process, CoN both delays and discourages the development of new facilities in outlying areas. Furthermore, CoN laws do not provide any additional incentives to medical providers to locate in areas where they cannot raise the revenue to sustain their business.[5]

It has been observed that CoN reduces the overall quality of care by inhibiting the availability of higher-quality forms of health care delivery. Even absent political pressure, a government body is inherently unable to strike the proper balance between access and safety for millions of patients across billions of encounters with medical personnel. Such an authority would inevitably restrict access to care and block innovations that make healthcare better, cheaper, and safer.[6]

[5] Valone P, Certificate of Need: Access Denied, 19 September 2011, available at http://www.nccivitas.org/2011/certificate-of-need-access-denied/

[6] Cato Handbook for Policymakers 7th ed http://object.cato.org/sites/cato.org/files/serials/files/cato-handbook-policymakers/2009/9/hb111-15.pdf

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2. Certificate of need is not effective in controlling health care costs

In the USA a core intention of the CoN was to manage healthcare costs. There have been numerous academic studies regarding the effects of the CoN on the cost of healthcare. Virtually no studies have shown that the CoN lowers costs.[7] One study performed by Conover and Sloan in 1998 found that "mature certificate of need programs resulted in a slight (2 percent) reduction in bed supply but higher costs per day and per admission, along with higher hospital profits."[8]

In 2004 the US Federal Trade Commission and the Department of Justice both claimed that CoN programs actually ***contribute to rising prices because they inhibit competitive markets***, which should otherwise be operating to control the costs of care and guarantee quality and access to treatment and services.

3. Certificate of need hampers the introduction of new health technologies

CoN provisions have been subject to wide criticism. It is argued that CoN programs operate to reduce price competition between facilities, and raise the barriers of entry to potential new competitors into the market.[9]

The principle of competition relies on the fact that there is a certain degree of excess capacity within a market. The CoN system attempts to eliminate that excess capacity from the system. As such it is in direct opposition to competition principles where ideally, supply should not exactly match demand but should be slightly greater. If supply exactly matched demand there would be no competition because the system would be in equilibrium. In real terms such equilibrium is not only unfeasible, it is undesirable because it stifles innovation and exploration of new and more efficient ways of achieving access to healthcare services.[10]

[7] Kavanagh K.T., The Certificate of Need: An Outdated Concept in Need of Re-Examination http://www.healthwatchusa.org/publications/2009-Certificate_of_Need-Final-4.pdf.
[8] Conover, C.J., & Sloan, F.A. (1998). Does removing certificate-of-need regulations lead to a surge in health care spending, Journal of Health Politics, Policy and Law, 23, 455-81.
[9] US Federal Trade Commission and the Department of Justice, Competition in Healthcare and Certificates of Need, 2008, available at http://www.justice.gov/atr/public/comments/233821.htm.
[10] Caudill S.B., Ford J.M, Kaserman, D.L. Certificate of Need Regulation and the Diffusion of Innovations: A Random Co-Efficient Model, Journal Of Applied Econometrics, Vol. 10, 73-78 (1995)

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4. Certificate of need does not improve the distribution of healthcare services

There is no evidence that the certificate of need programme increases access to care. The proponents believed that CoN had only added to health costs by bureaucratizing the planning process and obstructing the development of integrated delivery systems.

HASA is of the view that the certificate of need provisions of the National Health Act were ill-conceived from the inception as they were based upon an already floundering American concept that has since been proven to be largely unsuccessful in its land of origin, which is the reason why these provisions of the National Health Act had never been brought into effect.

It is against this backdrop that the DOH should reflect on the long-term consequences of any potential regulations introduced in the context of CoN.

Conclusion

The cumulative effect of the aforementioned points lead us to the conclusion that it will be in the best interest of all stakeholders, including the DOH, that the CoN provisions be repealed.