NETCARE LIMITED

PROPOSED REGULATORY INTERVENTIONS FOR LICENSING

1 March 2018

Background:
Challenges facing the provision of healthcare in South Africa

The current South African regulatory regime governing private healthcare needs to be considered against the backdrop of the current challenges facing healthcare in South Africa being:

- A high and increasing quadruple burden of disease and an ageing population within medical schemes;
- Significant reduction in the number of beds in the public sector notwithstanding population growth and severe challenges facing public healthcare;
- A chronic shortage of medical professionals including nurses and doctors (particularly specialists) in both the public and private sector; and
- An inflexible and inefficient regulatory and administrative regime (including the HPCSA) that constrains innovation, limits competition and results in increased costs and prevents hospitals from being able to react quickly to increased demand.

Background: Impact of the regulatory regime

- Private hospitals are required to operate within the parameters and constraints of the current regulatory framework.

- As a consequence of the existing regulatory regime, there are inefficiencies which arise, which are beyond the control of private hospitals.

- Existing regulations restrict efficiencies in a number of ways. For example:
  - Private hospitals cannot employ doctors.
  - Private hospitals cannot source medicines in the most cost-effective manner.
  - Private hospitals cannot train doctors and are restricted in certain provinces in the number of nurses which they can train.
  - Private hospitals cannot convert existing beds or expand existing hospital facilities without prior regulatory approval, which process is lengthy.

Focus of this presentation

- The legal framework
- Inconsistent application of the current licensing regime
- Certificate of need
- Licensing and the promotion of innovation
- Whether licensing creates barriers to entry
- The role of regulatory bodies in the licensing process
- Quality, monitoring and reporting
- Granting, review and renewal of licenses

Legal framework

- The HMI paper is premised on section 27 of the Constitution creating a right of access to healthcare and suggests that provincial and national departments (as regulators), should ensure increased access through effective regulation including the licensing process which must be aligned with the Constitutional mandate for access to healthcare services.

- Section 27(1) provides that “everyone has the right to have access to healthcare services” and section 27(2) requires the State to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this right.

- There is no legal foundation or judicial pronouncements in respect of the relationship between:
  - The progressive realisation of the rights in section 27; and
  - The licensing process applicable to private healthcare facilities.

Legal framework

- The HMI paper refers to the policy trajectory in South Africa towards Universal Health Coverage through the NHI which aims to address imbalances through achievement of equitable access to healthcare services consistent with the State's Constitutional obligations.

- The NHIS is the subject of a White Paper published on 30 June 2017. There is currently no clarity on the final structure of the NHIS or the parameters of Universal Health Coverage.

- No legislative prerogative requires equitable distribution or supply of facilities throughout South Africa as is suggested by the HMI.

- The licensing regime only requires an applicant to demonstrate that it is able to fulfil the legislative requirements for the license and not the fulfilment of section 27 of the Constitution.

Legal framework

- The HMI has indicated that it wishes to engage the Provincial Departments and the National Department of Health on a number of key observations.

- The licensing of private health establishments is the exclusive reserve of Provincial Governments pursuant to the applicable provisions of the Constitution.

- No national legislation deals with the licensing of private health establishments including the National Health Act.

- Without an amendment to the Constitution, to afford greater intervention by the National Department of Health in the licensing of private health establishments, such an intervention is not legally permissible and would be in contravention of the applicable provisions of the Constitution.

Inconsistent application of the regulations

- Inconsistent application results from:
  - The application of different regulations:
    - Most provinces apply Regulation 158
    - The Western Cape applies Regulation 187
  - The inconsistent application of the same regulations
- The application process in the Eastern Cape, Free State and KZN are characterised by:
  - Severe delays in processing both new applications and extensions
  - Adoption of criteria beyond those set out in the regulations
  - Imposition of criteria dictated by authorities on a case-by-case basis
  - Licensing processes are unpredictable, lengthy and in some cases contrary to the prevailing principles of administrative law

Reforming the licensing regime

- Netcare is of the view that, rather than replacing the current regime, certain reforms should be introduced to ensure proper, consistent, transparent and fair functioning of the existing regime.

- In a paper submitted in 2014, Netcare made several recommendations aimed at reforming the current licensing regime. These included the following:

  – A transparent and consistent regulatory regime should apply throughout the country, stipulating the specific factors which the regulators should take into account in determining whether or not to approve the application for a hospital licence (or a change in bed use).

  – Specific statutory time frames should be provided for the processing of applications, with approval of the application in question being the consequence of a failure to take a decision within the stipulated period.

  – Applications should not be required for extensions of existing facilities or changes of use of beds within existing facilities.

Reforming the licensing regime

- Recommendations (continued):
  - Regulators should provide reasons for their decisions (in accordance with the provisions of the Promotion of Administrative Justice Act).
  - The regulatory regime should focus on ensuring that prospective facilities meet the requisite clinical standards and are able to provide the appropriate quality of care and should not involve assessments of “necessity” or “need”, which are inherently investment-driven decisions.

- In addition to the recommendations previously proposed, it is suggested that provinces should be required to account for:
  - The number of applications received per year
  - The number actually processed
  - The number pending (including the length of the delay in processing and the reason for the delay)

Reforming the licensing regime

In 2014, HASA was requested by the Director-General to make submissions in relation to the proposed regulations in relation to the certificate of need and, in so doing, made some recommendations in relation to the licensing regime. These included the following:

- National regulation (with application decentralised to the provinces) to ensure consistency
- Independently governed process subject to objective criteria which are consistently applied
- Requirements and evaluation criteria should be transparent, rational, objective and clear
- The adjudication panel should be properly qualified
- A fair appeals process should be available
- A fair consultative process should be implemented which is designed to involve all interested and affected parties
- Fixed time frames
- Cost of applications should be kept low to encourage competition through new investment
- The process must promote competition

Certificate of need and universal health coverage

- Chapter 6 of the NHA introduced the certificate of need.
- Section 36 – 40 of the NHA are not yet in force, primarily due to the absence of supporting regulations. However, it has been raised in the HMI paper and we have therefore dealt with it in our submission.
- The certificate of need has no bearing on the licensing of private healthcare facilities.
- The HMI paper appears to incorrectly conflate the two processes.
- The certificate of need (which is governed by national legislation) is a distinct process to the licensing process (which is administered provincially).
- The certificate of need is in addition to the licensing process.

Certificate of need and universal health coverage (HASA submission)

In its 2014 submission to the Director-General, HASA made a number of important points in relation to the certificate of need:

- There are considerable regulatory and logistical factors necessary to implement the certificate of need provisions, given the number of establishments to which it would apply.

- The private sector seeks to increase access to healthcare and to mitigate the demand on the public sector. In this way it is no different to private health sectors around the world.

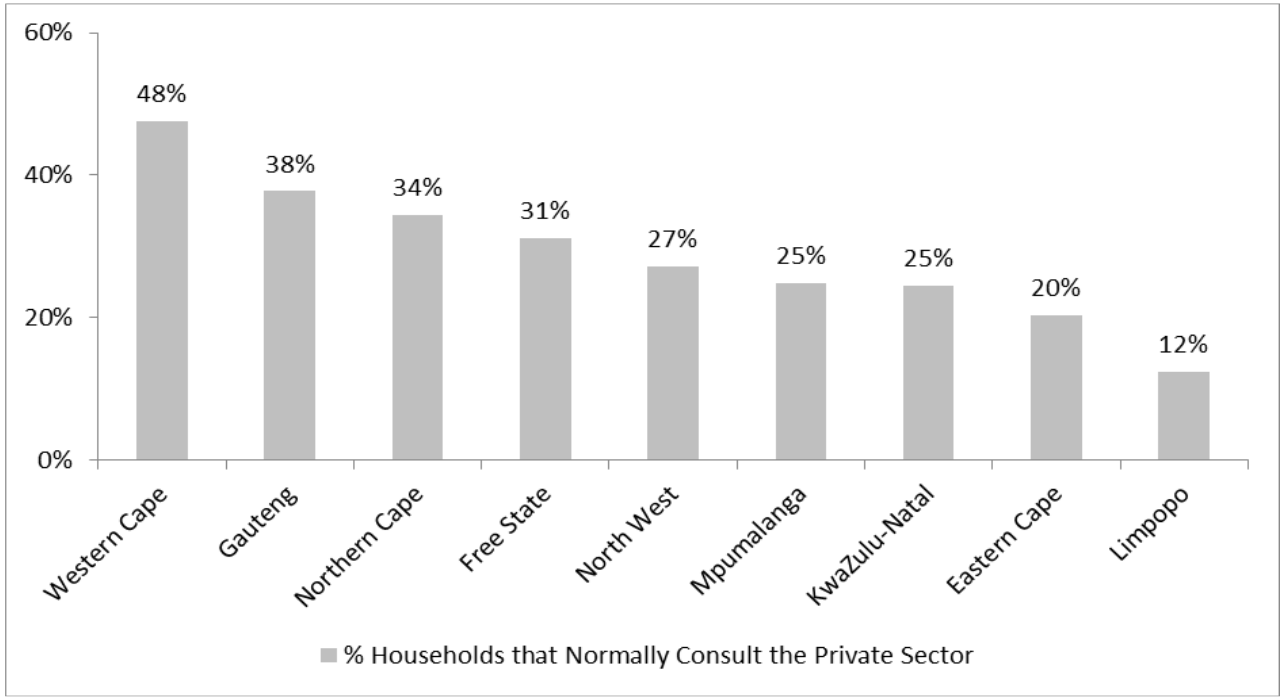
- South Africans who access the private healthcare sector choose to do so and a significant proportion of them do so through third party payers.

- Demand is not uniform throughout South Africa but it very closely tracks employment figures.

Certificate of need and universal health coverage (HASA submission)

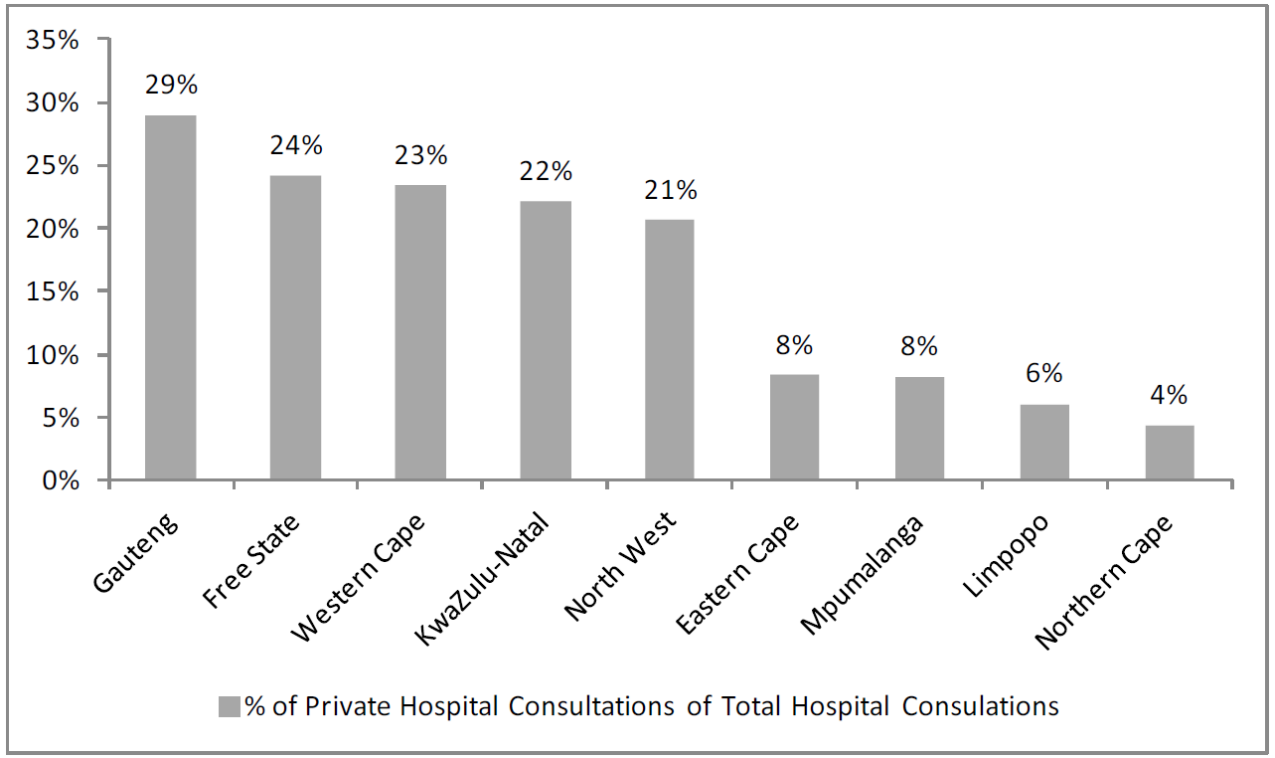
Percentage of households that normally consult the private sector by province

(StatsSA General Household Survey, 2012)



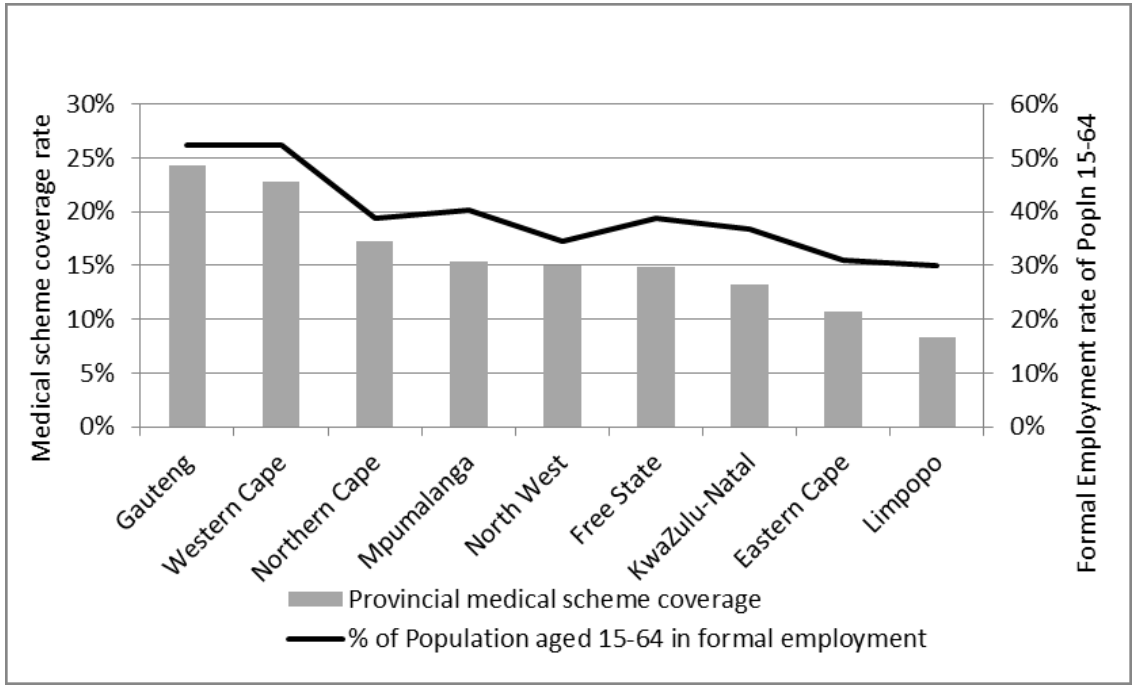
Certificate of need and universal health coverage (HASA submission)

Percentage of households that normally consult private hospitals compared to public hospitals by province (StatsSA General Household Survey, 2012)



Certificate of need and universal health coverage (HASA submission)

- Medical scheme coverage rate by province and percentage of population aged 15-64 in formal employment by province (CMS Annual Report, 2012 and Labour Force Survey, 2012)



Certificate of need and universal health coverage (HASA submission)

- Current licensing regime is fragmented and this will not be resolved by the introduction of a certificate of need.

- A certificate of need will not resolve the fact that:
  - Different provinces apply different regulations;
  - Regulations are inconsistently applied – even where provinces apply the same regulations, they place their own interpretation on the requirements and procedures; and
  - Some administrators have in the past developed their own internal policy documents.

- The inconsistent application of the regulations is not rectified by the introduction of a certificate of need but rather the introduction of a number of reforms to the licensing process.

Certificate of need and universal health coverage (HASA submission)

HASA in its submission to the Director-General suggested that the licensing regime should:

- Not apply to medical professionals who are already over-regulated.
- Not apply to medical technology unless compelling and rational reasons can be provided for doing so.
- Provide a bridge from the current to the new regime which:
  - Secures the rights of existing establishments; and
  - Ensures continuity of access to healthcare services.
- Not be subject to a time limitation as a short duration license:
  - Increases the cost of healthcare delivery; and
  - Discourages investment.

Certificate of need and universal health coverage (HASA submission)

- HASA pointed out that the USA introduced a certificate of need system in the 1970s which, over time, has shown that:

  - It has adversely affected access to healthcare services;
  - It is not effective in controlling healthcare costs;
  - It has hampered the introduction of new technologies; and
  - It does not improve the distribution of healthcare services.

- According to the HASA submission to the Director-General, the certificate of need provisions were ill-conceived and based on a US concept which has proved to be largely unsuccessful. It proposed that the provisions relating to the certificate of need be repealed.

Certificate of need and universal health coverage

- Lastly, in relation to the certificate of need, there are a number of aspects of the HMI paper which require further clarification:

  - There is no definition or clarity in relation to “underserviced markets”:
    - Which markets is the HMI referring to? In what manner are they underserviced? In relation to healthcare facilities or healthcare providers or both?
    - In this regard, it should be borne in mind that particular healthcare expertise is scarce in **all** markets, including urban areas.

  - If it is suggested that applicants should be required to apply for licenses in “underserviced areas” in order to ensure “equitable distribution of healthcare facilities”, then Government is able to enact the relevant sections in the NHA but it has not done so, presumably on the basis that a Constitutional challenge may be launched based on an unjustified and unreasonable limitation of rights.

Certificate of need and universal health coverage

- Effecting legislative changes based on what is “envisaged” under the NHI is premature and unreasonable. There is currently no clarity on the final structure of the NHI or the roles of regulatory bodies in the NHI.

- The connection drawn by the HMI between Universal Health Coverage through the NHI, equitable access, the State’s constitutional obligations and the licensing of private hospitals, is misconceived.

- The only way to attract capital to deliver private healthcare is to cater for the sector of the population which is willing to pay for it. That portion of the population does not reside across the country in an equitable fashion. A consideration of the equitable distribution of healthcare facilities as a means of ensuring equitable access is particularly relevant to the public sector.

Licensing and innovation

- The HMI suggests that Regulation 158 is primarily relevant to establishment of acute facilities and limits the establishment of novel facilities.

- In order to resolve this it would be necessary to amend Regulation 158 to take into account "*novel facilities*" and to provide definitive criteria in this regard.

- Simply introducing an element of *"innovation" to the licensing process* will allow authorities to adopt their own criteria leading to vagueness and indeterminate criteria, when certainty is what is required.

- The introduction of "*novel*" facilities does not necessarily mean that healthcare services will improve. The quality of healthcare services is dependent on a range of other factors.

Licensing and innovation

- In response to the suggestion that day facilities and HMO's are scarce in South Africa, it should be noted that:
  - Day cases generally occur in the acute setting in South Africa and make up approximately 50% of surgeries conducted in Netcare facilities.
  - HMO's have been discouraged in SA by the Health Professions Council.
- The HMI has suggested the introduction of innovation in the context of the NHIS. Again, this is premature in circumstances where the precise structuring of the NHIS has not yet been finalised. Once it is finalised then a debate can be had regarding innovation and whether it has a place in the NHIS.
- Lastly, the HMI has laid no foundation for suggesting that innovation should be overseen by a regulator. To do so may have a number of unintended consequences including the fact that a regulator would have an impact on change and innovation within the industry which may not be desirable.

Barriers to entry

- The HMI paper seems to proceed from the assumption that the licensing regime heightens barriers to entry and expansion in the healthcare market.
- It is difficult to respond to this as no evidence has been provided in this regard.
- However, there appears to be very little evidence of this if consideration is given to the number of new hospitals established in recent years and evidence of increasing numbers of licensed beds.
- 26 new hospitals have been built in the last 10 years:
  - NHN – 15
  - Mediclinic – 4
  - Netcare – 3
  - Life – 3
  - Clinix - 1
- New beds approved but not yet built: **7894**
- New beds under construction: **1506**

The role of regulatory bodies

- The HMI paper suggests that under the NHI, the OHSC will be the regulatory body responsible for licensing and accreditation of both public and private healthcare facilities.

- The OHSC is established in terms of section 77 of the NHA which has not as yet come into force. It is intended to oversee quality requirements and standards set by it.

- The mandate of the OHSC is not the administration of licensing of private health facilities.

- To imbue the OHSC with licensing functions would be *ultra vires* the NHA and unlawful.

- Secondly, the HMI paper suggests that streamlining of regulatory bodies (the OHSC, the CMS and the HPCSA) is necessary to address regulatory fragmentation in licensing and accreditation of health establishments. None of the regulatory bodies mentioned are responsible for licensing of private healthcare facilities and it is therefore unclear what is meant by the HMI in this regard.

Quality, monitoring and reporting

- The HMI has suggested that monitoring and reporting of facility capacity and distribution is weak.
- No evidence has been provided in this regard.
- The NHA contains provisions which enable provincial departments to interrogate facility capacity and to conduct monitoring and reporting including, inter alia, section 25(2)(n) of the NHA.
- Furthermore, it is not correct to say that there is no current database of current facilities, type of facilities, number of beds, areas of distribution and extent of use:
  - The number and type of facilities, number of beds and areas of distribution is all information contained in license applications and is provided to the departments responsible for granting licenses.
  - In relation to the extent of use, all facilities are required to report on their occupancy on an annual basis.

Granting, review and renewal of licenses

- The HMI paper contains a number of inaccuracies in relation to the granting, review and renewal of licenses:
  - Licenses for the establishment of a new facility or expansion of an existing facility require that the building/expansion be completed within a specified time period, failing which the applicant loses the right to build or expand the facility.
  - Facilities are subject to inspection on an annual basis. If a facility is found not to comply with the required standards, the facility's license could be withdrawn.
  - An adequate remedy is therefore available to manage quality standards.
- Granting short duration licenses would make it extremely difficult to secure the requisite capital investment to build hospitals in the first place, as investors would be understandably hesitant to invest in a hospital if the license were only granted for a short duration.
- Proper monitoring rather than short duration licenses would be more effective in ensuring that quality standards are met without discouraging investment.

Conclusion

- Netcare supports recommendations which would reform the licensing regime on the basis that:
  - it is transparent and consistent;
  - it specifies the factors which regulators will take into account in considering applications;
  - it contains statutory timeframes for the processing of applications; and
  - it accords with the principles of administrative law ie. in which regulators are required to provide reasons for their decisions.

- However, we wish to reiterate the additional recommendations made by Netcare in its submissions to the HMI in 2014, namely:
  - that applications should not be required for extensions of existing hospitals or change of use; and
  - The regulatory regime should focus on ensuring that prospective facilities will be able to meet the requisite clinical standards and provide the appropriate quality of care, rather than focus on assessments of necessity or need.