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Healthcare Market Inquiry
Attention : Clint Oellerman

By email : clinto@compcom.co.za

28 February 2018

Dear Clint

HEALTHCARE MARKET INQUIRY : SUBMISSION IN RESPONSE PROPOSED REGULATORY INTERVENTIONS FOR LICENSING OF HEALTH FACILITIES

1. We refer to the document dated 14 February 2018 which was circulated to stakeholders on 15 February 2018 entitled "*Proposed Regulatory Interventions for Licensing of Health Facilities : Discussion between Health Market Inquiry, National Department of Health, Provincial departments and Relevant Stakeholders"* ("**the Discussion Paper**"). We note that the Discussion Paper calls for submissions by 21 February 2018. In this regard, we record that we have requested, and been granted, an additional five business days within which to submit this response.

2. In October 2014 Netcare made submissions to the HMI regarding the regulatory framework applicable to private healthcare facilities in a paper entitled "*The Regulatory Regime – Impact on Competition and on Costs"* ("**Netcare's 2014 regulatory submission**"). The paper dealt with a number of

concerns pertaining to the regulatory regime, including concerns relating to the process of licensing hospitals[1] and should be read together with this submission.

3. As stated in Netcare's 2014 regulatory submissions, the current licensing process is cumbersome, inefficient and non-transparent. However, notwithstanding its shortfalls, Netcare is of the view that the existing licensing framework should be retained, but that a number of reforms should be introduced to the licensing process in order to render it less burdensome and opaque. Netcare's 2014 regulatory submission sets out recommended reforms, which Netcare believes would significantly improve the application process. It bears repeating those recommendations here:

3.1 firstly, Netcare suggests that 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 an application;

3.2 secondly, specific statutory timeframes should be provided for the processing of applications, on the basis that an application will be deemed to be approved in the event of a failure to take a decision within the stipulated period provided for in the legislation[2];

3.3 thirdly, applications should not be required to be submitted for extensions of existing hospitals facilities or changes of use of particular types of beds within existing facilities;

3.4 fourthly, the regulators in question should provide reasons for their decisions (in accordance with the provisions of the Promotion of Administrative Justice Act); and

3.5 lastly, the regulatory regime should focus on ensuring that prospective facilities meet the requisite clinical standards and should not involve assessments of "*necessity*" or "*need*", which are inherently

[1] See pages 21 to 32 of Netcare's 2014 regulatory submission.

[2] As stated in Netcare's 2014 regulatory submission, this accords with the approach which is adopted in relation to intermediate mergers in the merger control provisions of the Competition Act.

vague and uncertain criteria, are not particularly well-suited in the context of hospital licensing arrangements and involve economic judgments best left to investors.

4. In addition to reiterating Netcare's views on the licensing regime and recommendations as set out in its 2014 regulatory submissions, Netcare intends in this submission to respond to the following seven aspects of the Discussion Paper which appear to be based in certain respects on incorrect or flawed assumptions:

4.1 the synopsis of the legal framework and the inconsistent application of the current licensing regime;

4.2 the comments made in the Discussion Paper in relation to the certificate of need;

4.3 the comments made in relation to the role of licensing in promoting innovation;

4.4 the suggestion that the licensing regime has created barriers to entry;

4.5 the role of regulatory bodies in the licensing process;

4.6 the issues of quality, monitoring and reporting; and

4.7 the granting, review and renewal of licenses.

5. We deal with each of these in turn below.

6. **The legal framework applicable to licensing of private hospitals and the inconsistent application of the current licensing regime**

7. The Discussion Paper sets out a "*Synopsis of the Legal Framework*" pertaining to the licensing of private healthcare facilities in South Africa. We wish to make the following comments in relation to the overarching legislative framework and the application of the current licensing regime.

8. Firstly, in relation to the HMI's synopsis of the legislative framework, it should be noted that the licensing of private health establishments is the exclusive preserve of Provincial Governments pursuant to the applicable provisions of the Constitution of the Republic of South Africa, 1996 ("**the**

Constitution"). To this end, no national legislation deals with the licensing of private health establishments, including the National Health Act No. 61 of 2003 ("**the NHA**"). 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 possible and would be in contravention of the applicable provisions of the Constitution.

9. The statement is made in paragraph 7 of the Discussion Paper that the progressive realisation of each person's right to healthcare services "*includes ensuring that inter alia health care facilities are able to provide health care services in an appropriate manner*." However, there is no authority for such a statement as no judicial pronouncement has been made in respect of the relationship between the progressive realisation of the right in section 27 of the Constitution and the licensing process applicable to private health establishments.

10. In addition, the statement, in paragraph 7 of the Discussion Paper, that *"[t]he direct implication of section 27 is that the National and Provincial Departments of Health, as the regulator in this regard, should ensure increased access to quality healthcare, through effective regulation of healthcare facilities, among other things*", is without legal foundation. Once again, to proceed on the basis of a so-called "*direct implication*" of a section of the Constitution, that is yet to be judicially considered in such a context, is a legal conclusion without any foundation. In this regard, we refer the HMI to the submission entitled "*Legal Submissions on Behalf of Netcare Regarding the Rights of Access to Healthcare and Information in the Context of the Health Market Inquiry"* dated 25 February 2016 and prepared by David Unterhalter, Max Du Plessis, Andreas Coutsoudis and Ayanda Msimang which dealt with, *inter alia*, the following issues

10.1 the manner in which the right of access to healthcare services may be relevant to the HMI;

10.2 the meaning and content of the right of access to healthcare services;

10.3 the State's obligation to fulfil the right of access to healthcare services within the constraints of the Constitution; and

10.4 the private healthcare sector's role within the framework of the State's obligations in terms of section 27.

11. In response to paragraph 9 of the Discussion paper, while the National Health Insurance ("**NHI**") is currently the subject matter of a White Paper published on 30 June 2017, no clarity has been provided on the final structure of the NHI or the parameters and content of so-called "*Universal Health Coverage*." Therefore, the statement in paragraph 9 that *"[t]he NHI fundamentally aims to address prevailing imbalances through the achievement of equitable access to healthcare services, consistent with State's Constitutional obligations*", is without foundation in so far as such a principle is yet to be formally reflected, if at all, in the final design of a NHI for South Africa. Therefore, there is no current legislative prerogative that requires, as a matter of law, "*equitable distribution or supply of facilities throughout South Africa*." In any event, an equitable distribution or supply of facilities throughout South Africa is not achievable through a licensing regime as such a regime, in the ordinary course, merely requires a regulator to satisfy itself that an applicant is able to fulfil the legislative requirements of a license application and not the fulfilment of section 27 of the Constitution, which, ultimately, is to be fulfilled through the progressive realisation actions by the State and not the private sector.

12. As stated above, there are currently no provisions in the NHA in respect of the licensing of private health establishments. In the event that it was deemed necessary to introduce provisions relating to hospital licensing, then amendments to the NHA would be required. While section 23(1)(a) of the NHA does allow the National Health Council to advise the Minister of Health on policy in respect of the matters referred to in subsections (1)(a)(i) to (x), no such policy formally exists pursuant to the aforementioned section of the NHA.

13. Accordingly, for the reasons stated above, there is currently no legal basis to change the existing licensing regime, more particularly, on the basis that the existing regime does not promote the progressive realisation of the provisions of section 27 of the Constitution. As set out in its 2014 regulatory submissions, and repeated above, Netcare submits that rather than replacing the current regime, certain reforms should be introduced in order to ensure the proper, consistent, transparent and fair functioning of the existing regime. In this regard, the Hospital Association of South Africa

("**HASA**") in 2014 was informally requested by the Director General to provide input into the proposed regulations in respect of the certificate of need provisions ("**the HASA submission**"). (We deal with this in more detail below in relation to the certificate of need provisions contained in the NHA.) However, it is worth noting that, in its submissions to the Director General, HASA proposed that, at a minimum, the following reforms should be applied to the licensing regime:

13.1 The licensing system should be based on **national regulation** (with application decentralised to the provinces) to ensure consistency.

13.2 The process should be independently governed and subject to objective criteria which are consistently applied.

13.3 Requirements and evaluation criteria should be transparent, rational, objective and clear.

13.4 The adjudication panel should be appropriately qualified.

13.5 A fair appeals process should be available.

13.6 A fair consultative process should be implemented which is designed to involve all interested and affected parties.

13.7 The application process should be governed by fixed timeframes.

13.8 The cost of applications should be kept as low as possible to encourage competition through new investment.

13.9 The process must promote competition.

14. A full copy of this submission is attached marked "**A**".

15. In addition to this list, Netcare also suggests that license applications should be published for public comment by interested and affected parties to ensure further transparency and fairness in the licensing process.

16. Secondly, paragraph 8 of the Discussion Paper states that it is important to clarify whether any tension or conflict arises as a result of the concurrent national and provincial legislative competence in relation to healthcare licensing matters.

17. Furthermore, as stated in Netcare's 2014 regulatory submission, there is very clear tension which arises from the inconsistent application of the law[3]. This is best evidenced in the Eastern Cape, Free State and Kwazulu-Natal where licensing regimes are characterised by severe delays in the processing of both new applications and applications seeking an amendment to existing applications, the employment by licensing authorities of criteria beyond that set out in the applicable regulations (bearing in mind that the Free State now employs regulations other than R158), and the imposition of requirements that applicants meet criteria that are unilaterally dictated by the authorities on a case-by-case basis. Consequently, from province to province irregularities occur that frustrate applicants and the overall application procedure. In addition, any alleged barriers to entry are not formed by existing regulation but rather the actions and inaction of the regulatory authorities of not enforcing or adhering to the requisite regulations and endeavouring to reserve to themselves the right to dictate criteria that are *ultra vires* the particular regulatory regime in place. Licensing and application procedures are therefore, in the main, unpredictable, delayed, unduly lengthy and contrary to prevailing principles of administrative law. Provincial authorities should be called upon to account for the number of applications received in the period of a year, the number actually processed and the number of applications pending and, in respect of the last-mentioned category, the length of, and cause for, the delay.

18. Based on what is stated above, the legal framework applicable to the licensing of private health establishments is adequate to address matters of access to healthcare, whether novel or standardised, as contemplated in section 27 of the Constitution. The issue is not the regulations but the implementation of the existing regulations. In addition, licensing procedures that do not adhere to the principles of administrative justice lie at the root of difficulties experienced by newcomers to the market who are subject to application procedures not sanctioned by existing regulation or whose

[3] See paragraphs 52 – 53 and 55 – 59 of Netcare's 2014 regulatory submissions.

applications are simply not processed and delayed for unacceptable periods of time with no justifiable cause or reason. Therefore, no matter the type of regulation, without proper adherence to the regulations in place and prompt and administratively acceptable regulatory responses to applicants, there will be no change to the prevailing market conditions in respect of both entry to the private healthcare market or in the equitable distribution of health care services in the Republic. This is not a debate about the content or type of regulations but the administrative competence to adhere to both the regulations in place and administrative law in general.

19. **Certificate of Need and Universal Health Coverage**

20. Chapter 6 of the NHA deals with the introduction of the so-called "*certificate of need*", which is a legislative concept contemplated in section 36 of the NHA. In addition, sections 37 to 40 contemplate the supporting infrastructure for purposes of administering the certificate of need as contemplated in the NHA. While the Minister of Health has acted to classify hospitals pursuant to the provisions of section 35 of the NHA, no competent legal action has been taken to introduce sections 36 to 41 of the NHA into law. This is primarily due to the absence of supporting regulations as contemplated in sections 39(1) and (2) of the NHA. The certificate of need has no bearing on the licensing of private health establishments. The process in respect of applying the provisions of sections 36 to 41 is thus distinct from a licensing regime, which is evidenced by the fact that there is a particular appeal process, in respect of the granting or refusal to grant a certificate of need, in section 38 of the NHA. Therefore, the NHA contemplates the certificate of need process as one distinct, and in addition to, a licensing process as currently administered provincially.

21. Whilst there is a reference in paragraph 12 of the Discussion Paper to an "*amended CON*", no amendments have been effected to sections 36 to 41 of the NHA and the sections remain legally inert.

22. While it is common cause that the certificate of need provisions of the NHA, were declared invalid and set aside, given that this has been raised by the HMI in the Discussion paper, it is important to consider the concept of the certificate of need more generally, and the negative impact it may have on the private healthcare industry as a whole.

23. As mentioned above, HASA made a submission to the Director General in relation to the certificate of need provisions contained in the NHA. In summary, HASA's commentary made the following important points in relation to the certificate of need provisions:

23.1 The considerable regulatory and logistical factors necessary to successfully implement the certificate of need provisions are underestimated, given the number of health establishments and the various providers of health services in the country to which the certificate of need regime would apply.

23.2 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 and increases access to healthcare. South Africans choose to access healthcare in the private sector rather than the public sector and a significant proportion of them pay for private healthcare through third party payers.

23.3 The demand for private healthcare is not uniform throughout South Africa. It is highly variable across provinces with those who are formally employed having the means to purchase private healthcare services. For example, in the Western Cape, 48% of households normally access private healthcare, while only 12% of households in Limpopo normally access the private healthcare sector. Similarly, the percentage of households that would normally access a private hospital range from 29% of households in Gauteng to 6% of households in Limpopo.

23.4 The current hospital licensing regime is not only fragmented in that different provinces apply different regulations, but it is also inconsistently applied in that, even where provinces apply the same regulations, they place their own interpretation on the requirements and procedures. Some administrators have in the past created their own internal policy documents, which resulted in further inconsistency in the application of the regulations.

23.5 The inconsistent application of the regulations is not remedied by introducing a certificate of need, but rather by the introduction of a number of reforms.

23.6 In addition, HASA is of the view that a new licensing regime should:

23.6.1 Not apply to medical professionals who are already the most regulated professionals in South Africa. Any further regulation will lead to medicine becoming a less attractive career option in circumstances where there already exists a dire shortage of medical professionals.

23.6.2 Not apply to medical technology (unless compelling and rational reasons can be provided for doing so).

23.6.3 Provide a bridge from the current regime to the new regime which does not unfairly limit rights of existing licensees and operates to secure the rights of existing establishments and ensure the continuity of access to health services.

23.6.4 Not be subject to a time limitation as a licence of shorter duration increases the cost of healthcare delivery and discourages investment in the healthcare sector.

23.7 The United States of America introduced a so called certificate of need system in the 1970s which has, over time, shown that:

23.7.1 **The certificate of need has adversely affected access to healthcare services.** It forces potential medical professionals to go through an application process creating delays and discouraging the development of new facilities in outlying areas. The certificate of need provisions do not provide any additional incentives to medical providers to locate to areas where they cannot raise the revenue to sustain their businesses. In addition, it has been observed that the certificate of need reduces the overall quality of care by inhibiting the availability of higher quality forms of health care delivery.

23.7.2 **The certificate of need is not effective in controlling healthcare costs.** There have been numerous studies in the USA regarding the effects of the certificate of need on the cost of healthcare, however, virtually no studies have shown that the certificate of need lowers costs.

23.7.3 **The certificate of need hampers the introduction of new health technologies.** The certificate of need provisions operate to reduce price competition between facilities and increase barriers to entry. The certificate of need system attempts to eliminate excess capacity

from the system and, as such, is in direct opposition to competition principles where ideally, supply should not be equal to demand, but should rather be greater.

23.7.4 **The certificate of need does not improve the distribution of healthcare services.** The certificate of need adds to healthcare costs by bureaucratising the planning process and obstructing the development of integrated delivery systems.

23.8 HASA states in its submission to the Director General that it is of the view that the certificate of need provisions in the NHA were ill-conceived as they were based on the American concept which has proved to be largely unsuccessful. HASA, accordingly, proposed to the Director General that, given the long-term consequences of any potential regulation including a certificate of need, it would be in the interests of all stakeholders that the certificate of need provisions be repealed.

24. In addition to the submissions made by HASA to the Director General, Netcare wishes to raise a few additional concerns in relation to the possible reintroduction of the certificate of need provisions.

25. Firstly, reference is made in paragraph 19 of the Discussion Paper to "*underserviced markets*". However, no clarity is provided by the HMI regarding the nature of these markets or in what manner they are underserviced - whether by the absence of healthcare facilities or healthcare providers or both – bearing in mind that even particular healthcare expertise is scarce in affluent markets and urban areas.

26. Secondly, in so far as requiring applicants to apply for licenses to operate private health establishments in underserviced areas "*to ensure equitable distribution of healthcare facilities*", such actions would be *ultra vires* the NHA in so far as the certificate of need provisions of sections 36 to 41 already contemplate such a regime. Accordingly, if there is a desire to require applicants to make applications for the establishment of private health facilities in particular areas only, then Government is able, within the four corners of the Constitution, to enact sections 36 to 41 of the NHA. Such steps have not been taken by Government presumably out of concern that such steps would be challenged constitutionally with reference to unjustified and unreasonable limitations on the rights of applicants

and existing license holders in terms of, at least, sections 9 (equality), 18 (freedom of association), 22 (freedom of trade, occupation and profession) and 25 (property) of the Constitution.

27. Furthermore, as stated above, effecting changes to legislation in light of what is "*envisioned … under the NHI*" is premature and unreasonable in so far as there is no clarity on the final structure or architecture of the NHIS, or the roles of existing regulatory bodies under any final NHIS including the Office of Healthcare Standards Compliance ("**OHSC**"), the Council for Medical Schemes ("**CMS**") and the Health Professions Council of South Africa ("**HPCSA**").

28. Thirdly, the Discussion Paper draws a connection between the policy trajectory towards Universal Health Coverage through the NHI, the achievement of equitable access to healthcare services, the State's constitutional obligations and the licensing of hospitals. While the HMI appears to be suggesting that the licensing regime should be geared towards achieving these policy objectives and should be reformed or amended with the end goal of the NHI in mind, it should be borne in mind that the current position is that the public and private healthcare sectors are separate and distinct and, until such time as they may be unified under the NHI framework, the licensing of private hospitals remains a separate process. While the HMI appears to be seeking to position the licensing regime such that it contributes towards the realisation of a healthcare landscape consistent with the goals of the NHI ie. equitable distribution, its objectives are misplaced.

29. While the two sectors remain separate and distinct, the only manner in which to attract capital to deliver private healthcare is to cater for that sector of the population which is willing to pay for healthcare services. That sector of the population does not reside across the country in an equitable fashion and, accordingly, using the licensing process to ensure "*equitable distribution or supply of facilities throughout South Africa"* is impractical and unrealistic. This needs to be taken into consideration in the formulation of any new or amended licensing regime. It is submitted that a consideration of equitable distribution of healthcare facilities as a basis for ensuring equitable access to healthcare is, at this stage, only relevant insofar as the location of public healthcare facilities is concerned.

30. Finally, it is respectfully submitted that policy considerations relating to issues such as the certificate of need and how this may conceivably be related to policy objectives of the NHI, is outside the remit of the HMI's inquiry. The Terms of Reference of the HMI require it to consider "*the hospital licensing process and its influence on the market for hospital services*", not to engage in recommendations in relation to proposed healthcare policy objectives.

31. **The role of licensing in promoting innovation**

32. Firstly, if one accepts that "*Regulation 158 [as] drafted makes it primarily relevant for the establishment of acute based facilities, thus limiting the establishment of novel facilities which could introduce entry of innovative and cost-efficient models of healthcare delivery*", the answer, in so far as such a statement is correct, is then not to change the licensing regime but rather to amend Regulation 158 in order for it to take into account "*novel facilities*", rather than allow a subjective process in terms of which licensing authorities adopt their own criteria in this regard. It is submitted that the current licensing regime is already vague and fraught with inconsistencies in its application and by introducing an element of so called "*innovation*" to the criteria, which is open to vastly different interpretations, creates an even more vague and indeterminate set of criteria, rather than the certainty which is required.

33. It should also be noted that the mere introduction of "*novel facilities*" does not mean that healthcare services will improve. The provision of good quality healthcare services is not exclusively dependent on the facility from which the healthcare services are provided, but rather the nature of the healthcare service provided by and the expertise and availability of healthcare professionals.

34. Secondly, we note the absence of any authority for the statement, in paragraph 17 of the Notice, that "*day facilities and other Health Management Organisation type facilities are relatively scarce in South Africa and markedly lagging international trends.*" Day cases generally occur in the acute setting in South Africa and it is therefore not appropriate to reflect on comparators of the number of day facilities but, more importantly, the proportion of day case surgeries making up the total number of surgeries. Contrary to figures published which state that less than 10% of cases occur in day facilities, day cases make up approximately 50% of surgeries conducted in Netcare's acute facilities. With respect to HMO facilities, HMO's are effectively vertically integrated entities combining

medical scheme risk and administration as the profit centres and hospitals, pathology and other providers as cost centres. Netcare is fully supportive of vertically integrated healthcare models and has not only explored these avenues in other markets but has been involved in trying to build this very model in South Africa in the late 1990's and early 2000's, but was given a very firm indication from the head of the Health Professions Council that this structure was not accepted in South Africa, nor would it be acceptable. In response to the assertion made by the HMI in relation to day facilities and HMO's, Netcare is of the view that the scarcity of healthcare services in South Africa is not addressed by changing the existing licensing regime: economic conditions remain averse to encouraging investment in South Africa. No economic change will be brought about as to the accessibility of healthcare services for South Africans whether in urban or rural areas by amending the existing licensing regime.

35. Thirdly, with reference to the introduction of innovation in the context of the NHIS, it would be premature to plan around the introduction of "*innovative and cost-efficient models of healthcare delivery*" in the absence of certainty as to the precise structuring of the NHIS. Within the confines of the debates surrounding the architecture of the NHIS, will be a decision as to the particular type of healthcare delivery that is appropriate for South Africa with reference, presumably, to its particular burden of disease and the needs of its population. Only once the NHIS has been finalised or, at least, a structure has been agreed amongst participating stakeholders, is a debate concerning what is or is not "*innovative*" and whether or not its place is in the NHIS, appropriate.

36. The introduction of any revised licensing regime must take into account existing legislative powers, both at national and provincial level, to afford national and provincial authorities the ability to monitor the delivery of healthcare services within a particular area or province. One of the proposed regulatory interventions suggested by the HMI in the Discussion Paper is that the licensing regime should "*give preference to licensing new, improved and innovative models of care that develop the current system and improve cost-containment while offering high standards of care.*" There is no correlation between the progressive realisation of rights in terms of section 27 of the Constitution and a licensing model based on a preference for innovation. In addition, there is no evidence that current licensing models do not encourage the presentation of innovative models of care or that such models of care detract

from a developing system in respect of improving cost-containment whilst offering high standards of care.

37. Lastly, no basis is provided by the HMI for its suggestion that so called "*innovation*" should be overseen by a regulator. No consideration appears to have been given to the potential unintended consequences which may flow from such oversight, including the fact that the regulator would have a significant impact on change and innovation in the healthcare industry, which may not be desirable.

38. **The licensing regime and barriers to entry**

39. We note that in the introduction to the Discussion Paper the HMI states that "*most stakeholders raised concerns that the current licensing regime stifles competition and innovation; and further* ***heightens barriers to entry and expansion in the market***. *In particular, stakeholders raised the concern that the* ***relevant licensing regulations and how they are currently applied, results in barriers to entry and expansion*** *for smaller facilities and hampers entry of innovative models of healthcare delivery."* (our emphasis) The suggestion that the current licensing regime creates barriers to entry is repeated several times throughout the Discussion Paper.

40. It is difficult to critically assess the HMI's contention in this regard as the HMI has not provided any examples of the licensing regime having stifled competition and innovation, nor of it having resulted in barriers to entry and expansion for smaller facilities. Given that evidence has not been provided by the HMI to support its contentions in this regard, it is impossible to determine whether the issue complained of by stakeholders is not a case of the inefficient operation of the licensing regime as opposed to the creation of barriers to entry and the stifling of competition and innovation as alleged.

41. Netcare submits that, while the licensing regime is cumbersome, extremely inefficient and poorly administered, evidence would appear to indicate that it does not significantly increase barriers to entry. To the contrary, there is evidence of significant entry into the market in the last 10 years, (including the establishment of a significant number of new hospitals by smaller market participants), as well as evidence of increasing numbers of licensed beds, which appears not to be consistent with the HMI's assertion that the licensing regime heightens barriers to entry.

42. In the last 10 years, the following new private hospitals have opened across South Africa:

	Hospital	Opening date	Tertiary referral region	Hospital group
1	Ethekweni Hospital and Heart Centre	July 2008	Durban	NHN
2	Life Beacon Bay Hospital	Nov 2009	East London	Life
3	Mediclinic Cape Gate	Feb 2010	West Coast and Karoo	Mediclinic
4	Emalahleni Private Hospital	March 2011	Pretoria	NHN
5	Rustenburg Medi-Care	May 2011	Rustenburg	NHN
6	Netcare Waterfall City Hospital	July 2011	Johannesburg North and surrounds	Netcare
7	Hillcrest Private Hospital	July 2011	Durban	NHN
8	Life Piet Retief Hospital	Dec 2011	Pretoria	Life
9	Clinix Phalaborwa Private Hospital	June 2012	Polokwane	Clinix
10	Lowveld Hospital	June 2012	Nelspruit	NHN
11	East London Eye Hospital (Pty) Ltd	Oct 2012	East London	NHN
12	Quality Care Private Hospital	April 2013	Polokwane	NHN
13	Capital Oncology	Aug 2013	Durban	NHN
14	Mediclinic Strand	Oct 2013	Overberg	Mediclinic
15	Mediclinic Secunda	May 2014	Pretoria	Mediclinic
16	Mthatha Private Hospital	Oct 2014	East London	NHN
17	Botshilu Private Hospital (Soshanguve)	Oct 2014	Pretoria	NHN
18	Kiaat Private Hospital	Oct 2014	Nelspruit	NHN

19	Gateway Private Hospital	Dec 2014	Durban	NHN
20	Mediclinic Midstream	March 2015	Pretoria	Mediclinic
21	Busamed Paardevlei Private Hospital (RF)(Pty) Ltd	May 2015	Overberg	NHN
22	Netcare Pholoso Hospital	Sept 2015	Polokwane	Netcare
23	Life Hilton Private Hospital	Sept 2015	Pietermaritzburg	Life
24	Netcare Pinehaven Hospital	Oct 2015	Johannesburg North and surrounds	Netcare
25	Busamed Modderfontein Private Hospital	Sept 2016	Johannesburg North and surrounds	NHN
26	Busamed Bloemfontein Private Hospital	Feb 2018	Bloemfontein	NHN

43. As can be seen from the table above, only 10 of the 26 new hospitals (less than half) were commissioned by the three large hospital groups.

44. In addition, it is interesting to note the following statistics which indicate the number of new beds which have been approved, but not yet built or which are currently under construction:

	Approved but not yet built	**Under construction**
Greenfields	7056	1264
Brownfields	838	242
Total	**7894**	**1506**

45. In addition to the above, in relation to the issue of new entry and expansion, we refer also to the report prepared by Meg Guerin-Calvert of Compass Lexecon entitled "*Market Definition and Relevant*

Markets : Assessment of Competitive Alternatives" submitted to the HMI in October 2014 in which it was found that there was substantial pending entry and expansion at the time of the report.[4]

46. It does not appear from the evidence referred to above that the licensing regime, although inefficient, in fact creates a barrier to entry.

47. **The role of regulatory bodies in the licensing process**

48. Paragraph 13 of the Discussion Paper references, as part of the synopsis of the legal framework, section 47 of the NHA (which allows the Minister to prescribe quality requirements and standards) and the Norms and Standards Regulations (which were published on 2 February 2018) which introduced the OHSC. Neither section 47 of the NHA nor the regulations pertaining to norms and standards deal with matters relating to the granting or issuing of licenses in respect of operating or conducting a private health establishment. The OHSC is established in terms of section 77 of the NHA which has not even come into effect as yet. Furthermore, pursuant to its mandate as set out in the NHA, the OHSC will only be concerned with the application of norms and standards to be determined by it and not with the administration of the licensing of private health establishments.

49. Inexplicably, and notwithstanding that the OHSC is only mandated to deal with quality requirements and standards, the HMI in the section of the Discussion Paper entitled "*Possible Regulatory Interventions"* states that "*it is envisioned that under the NHI, **the OHSC will be the responsible regulatory body for licensing and accreditation of both public and private facilities**. In this regard, some streamlining between the relevant regulatory bodies such as the OHSC, CMS and the HPCSA, among others, is necessary, to address regulatory fragmentation in licensing and accreditation of different health establishments."* (our emphasis)

[4] See pages 294 – 309 of the report.

50. Firstly, it is not clear on what basis the HMI believes the OHSC will assume responsibility for licensing of private healthcare facilities but it is submitted that, to imbue the OHSC with licensing functions, would be *ultra vires* the NHA and thus unlawful.

51. Secondly, in relation to the latter part of the proposed intervention, it is not clear what the streamlining of regulatory bodies such as the OHSC, the CMS and the HPCSA has to do with licensing of healthcare facilities when none of those bodies are responsible for licensing of healthcare facilities. Furthermore, the HMI does not explain its suggestion that such streamlining will "*address regulatory fragmentation in licensing and accreditation of different health establishments.*"

52. **Quality, Monitoring and Reporting**

53. At paragraph 20 of the Discussion Paper, the HMI suggests that "*monitoring and reporting of facility capacity and distribution is weak*". We note that no evidence has been provided by the HMI to support such contention. Notwithstanding this, the ability of provincial departments to interrogate facility capacity is already contained in the NHA. In this regard, section 25(2)(n) of the NHA provides provincial departments with the power to "*control the quality of all health services and facilities*". Additional powers are also available to provincial authorities in order to deal with matters pertaining to the delivery of healthcare services within a particular province in terms of the NHA. Accordingly, the contents of paragraph 20 of the Discussion Paper do not form a basis for altering the existing licensing regime in so far as powers exist in terms of the NHA to address matters of monitoring and reporting.

54. Furthermore, the suggestion by the HMI that there is no obligation on facilities to report back periodically on issues of major policy concern and that there is no central database, either nationally or provincially, of current facilities (including types) and numbers of beds, areas of distribution and the extent of use by market players, is not correct. Firstly, the maintenance of a database of facilities and relevant information pertaining to those facilities would appear to be within the remit of the departments currently responsible for granting licenses, given that it is those departments which have access to the applications which contain all of the information which the HMI suggests should be contained in the database. Secondly, in relation to the extent of use of healthcare facilities, we are

advised that all facilities are required to report on their occupancy on an annual basis. Accordingly, a database of such reports must be available from the relevant authority.

55. **Granting, review and renewal of licenses**

56. The Discussion Paper, at paragraphs 21 to 22, makes a number of statements regarding the granting, review and renewal of licenses, which are not correct.

57. The HMI contends at paragraph 21 that it has observed no requirement that new licenses be commissioned within a certain period and that this leads to a sub-market for the sale of licenses. This is not correct. We are advised that licenses granted for the establishment or expansion of a facility do in fact contain a requirement that building or expansion of the facility be completed within a specified time period after the granting of the licence. We understand that Netcare has in fact lost the opportunity to expand a particular facility on the basis that it did not commence with the expansion within the time period specified in the licence.

58. At paragraph 22, the HMI states that there are no requirements for review and renewal of licenses. This, too, is incorrect. We understand that facilities are subject to inspection on an annual basis and, in the event that a facility is found to not comply with the required standards, that facility's licence could be withdrawn. Accordingly, the HMI's suggestion that the granting of licences in perpetuity "*robs"* the market of a management tool to ensure appropriate quality care is not only highly concerning, but also incorrect, as the licence of a facility which does not meet the requisite quality standards could be withdrawn. Furthermore, in the event that licences were not granted in perpetuity, it would become difficult to secure the requisite capital investment to build hospitals in the first place as investors would understandably be hesitant to invest in a hospital if that hospital were only granted a licence for a short period of time. It is submitted that proper monitoring of compliance with standards would be a more effective measure to ensure that quality standards are met and would not mitigate against continued investment in private healthcare.

59. **Conclusion**

60. In conclusion, Netcare supports the recommendations by the HMI of a transparent and consistent regulatory regime which is applicable nationally, which specifies the factors which regulators will take into account in considering applications and in relation to which statutory timeframes are provided for the processing of applications. Furthermore, Netcare is in agreement with the HMI that regulators should be required to provide reasons for their decisions, in accordance with the Promotion of Administrative Justice Act.

61. However, we wish to reiterate the recommendations made in Netcare's 2014 regulatory submission in relation to the reform of the hospital licensing regime which have been repeated above.

62. In addition, we note that the HMI states in paragraph 3 of its submission that it wishes to engage further with the Provincial Departments and the National Department of Health. Netcare proposes that in its discussions with the provincial and national departments, the HMI should seek to encourage the departments to pursue reforms which will result in an open, transparent, clear and efficient licensing process which is applied consistently to all applicants across the various provinces.

63. Lastly, we note that the HMI's Discussion Paper deals only with regulatory concerns relating to the licensing of private healthcare facilities. We wish to reiterate that there are a number of other concerns which were raised by Netcare in its 2014 regulatory submissions in relation to the regulatory aspects pertaining to the following:

63.1 the building regulations applicable to the establishment of healthcare facilities;

63.2 regulations pertaining to the employment of doctors and participation in multidisciplinary practices;

63.3 aspects of the regulatory regime which result in the shortage of doctors and nurses in South Africa; and

63.4 regulation which impacts upon expenditure on pharmaceuticals and surgicals.

Yours sincerely

[UNSIGNED DUE TO ELECTRONIC TRANSMISSION]

Anthony Norton/Michelle Rawlinson
NORTONS INC.