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Health Market Inquiry

Promoting Healthy Competition

SEMINAR:

PROPOSED REGULATORY INTERVENTIONS FOR LICENSING OF HEALTH FACILITIES

Discussion between Health Market Inquiry, National Department of Health, Provincial Departments and Relevant Stakeholders.

14 February 2018

INTRODUCTION

1. The licensing regime for healthcare facilities and how it affects competition in the private healthcare sector is among the subjects that was canvassed extensively during the conduct of the Health Market Inquiry ("HMI"). The HMI received numerous submissions from stakeholders across the sector highlighting concerns with the current regulatory framework for licensing. This was also dealt with extensively at the public hearings.

2. 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.

3. This document outlines the key observations which the HMI Panel wishes to engage further with the Provincial Departments and the National Department who have concurrent legislative competence in terms of the Constitution in relation to health services, particularly, licensing matters[1]. A further engagement with other relevant or affected stakeholder will take place.

4. In order to facilitate a candid dialogue, the HMI will hold a targeted session with the Provincial Departments and the National Department to clarify some of the policy issues on 28 February 2018. Further, on 1 March 2018, the discussion will continue with participation from other relevant or affected stakeholders, including Healthcare Facilities.

5. The discussion is aimed at facilitating a way forward for proposed interventions for licensing of healthcare facilities. This should assist the HMI in framing appropriate recommendations on a suitable licensing regime that is aligned with the Constitutional mandate for access to quality healthcare services, promotion of competition and facilitation of new entry, as well as new and innovative models of healthcare delivery.

6. Stakeholders are invited to make submissions on the observations and the proposed remedies by the HMI. Submissions and responses to this document should be submitted to the HMI by **21 February 2018** to the following email address:

   PaulinaM@compcom.co.za ; or MapatoR@compcom.co.za .

[1] Schedule 4 Part A of the Constitution.

SYNOPSIS OF THE LEGAL FRAMEWORK

7. The Constitution mandates the State and its organs to achieve the 'progressive realisation' of each person's right to health care services. This includes ensuring that *inter alia* health care facilities are able to provide health care services in an appropriate manner. The 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. In this regard, the conditions linked to the licensing process have to be consistent and aligned with the Constitutional mandate for access to healthcare services.

8. In light of the concurrent national and provincial legislative competence in relation to healthcare licensing matters, it is important to clarify whether any tension or conflict arises. In this regard, both National Parliament and Provincial Legislatures have the power to make laws in matters concerning licensing of healthcare facilities. The result of this legislative scheme is that the National Health Act[2] (NHA) is the national legislation while provinces have their respective provincial regulations dealing with licensing. However, in order to mitigate against any potential conflict between national and provincial laws, provinces must tailor their provincial legislation to fit into the national framework. Further, there must be effective co-ordination between the Minister and MECs in health policy development and implementation[3].

9. The policy trajectory in South Africa is the achievement of Universal Health Coverage (UHC) through the National Health Insurance framework (NHI). The NHI fundamentally aims to address prevailing imbalances through the achievement of equitable access to healthcare services, consistent with State's Constitutional obligations. This includes, ensuring equitable distribution or supply of facilities throughout South Africa.

10. The NHA is key to giving effect to the right of access to healthcare. The functions of Provincial Departments in terms of the National Health Act is to implement national health policy, norms and standards within the relevant provinces. The MECs must ensure *inte*r *alia*, that; health facilities are provided, health information systems are planned and managed, quality of health

[2] Act 61 of 2003.

[3] The spheres exercising concurrent legislative powers are obliged by the Constitution to do so based on principles of cooperative governance entrenched in sections 40 and 41 of the Constitution.

services and facilities is controlled, and that provincial health plans conform with national health policy.[4]

11. The NHA gives the Health Minister extensive powers, which includes introducing regulations, setting guidelines as well as national policy development and implementation.[5] Chapter 6 of the NHA deals with regulation of health establishments. Section 35 affords the Minister of Health the power to make regulations on the classification of Hospitals.

12. In April 2014, amendments to the NHA by introduction of sections 36 to 40 of the NHA *(i.e.* Certificate of Need (CoN) provisions) were proclaimed to ensure consistency of health services development in terms of national, provincial and municipal planning. These provisions were the subject of a court application brought by the President and were declared invalid and set aside by the Constitutional Court on the basis that they were made in error and irrational in law as they could not be implemented without promulgation of regulations, as this meant that health providers were engaging in criminal conduct as none of them were in a position to obtain the required certificate of need as long as the regulations had not taken effect.[6] This alarming situation had been brought to the attention of the Presidency, hence the application by the President to set aside the proclamation. As such, the amended CON provisions have not yet come into effect. This creates uncertainty with regard to the regulatory framework for healthcare licensing, which needs to be urgently resolved.

13. Section 47 also allows the Minister to prescribe quality standards. The Norms and Standards Regulations in terms of section 90(1)(b) and (c) introduced the Office of Health Standards Compliance (OHSC) which aims to guide, monitor and enforce the control of critical risks to health and safety in health establishments.

[4] Chapter 4 of NHA.
[5] Chapter 3 of the NHA.
[6] *President of the Republic of South Africa and Others v South African Dental Association and* Another [2015] ZACC 2.

OBSERVATIONS RELATING TO REGULATORY FAILURES IN HEALTH FACILITY LICENSING

14. Prior to 1993, licensing of facilities was administered centrally by the National Department of Health ("NDoH"), in terms of Section 44 of the Health Act of 1977. This changed when the interim Constitution (Act 200 of 1993) devolved the licensing process to provincial departments. The decentralised licensing process was retained in the final Constitution.

15. Regulation 158 of the Health Act (63 of 1971) regulates the process of licensing private health facilities. It is used by seven of the nine provincial departments of health, aside from the Western Cape and Free State. The Western Cape used Section 44 of the old Health Act to enact its own regulations, i.e. Regulation 187. The Free State repealed Regulation 158 and has, since 2014, relied on the Provincial Health Act to introduce its own licensing regulations.[7]

16. Stakeholders highlighted several difficulties with the licensing process, citing it as a barrier to entry and expansion. The HMI observes that the use of different regulations by the provincial departments is fragmented and thus creates inconsistencies in the interpretation and application of the license regulations. The provincial departments follow different approaches and use different criteria to evaluate applications for development or expansions of health facilities. Even for the provincial departments that use Regulation 158, there are variations in the application of the regulation.

17. Regulation 158 in its current form appears to be dated and not compatible with current market requirements. For example, the manner in which Regulation 158 is 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. This further frustrates entry by alternative providers that provide more cost-efficient models of healthcare delivery and that could challenge the traditional model of large general acute facilities. We note for example that day facilities and other Health Management Organisation type facilities are relatively scarce in South Africa and markedly lagging international trends. The HMI has been told that the cost-effectiveness of day hospitals and hospitals with new, more efficient formulas of delivery are not factors considered in the licensing process.

18. It has further been alleged that the impact on innovation is compounded by the fact that there is lack of coordination between various regulatory bodies, such as the Health Professions Council of South Africa ("HPCSA") and the Council for Medical Schemes ("CMS"), who are

[7] The HMI did not receive information from other provinces such as North West and Eastern Cape.

relevant in accrediting different players and health establishments who may wish to collaborate to offer innovative forms of care.

19. The HMI notes that, the current licensing framework, both in the public and private sectors, is not based on current or projected need. Further, it does not seem that equitable distribution of facilities is embedded in the licensing process, as we observe many underserviced markets, whereas licensing seems to favour markets with excess capacity. This is an area which the CON sought to remedy. The licensing framework is however currently administered by provinces with no standardised needs assessment (both qualitative and quantitative) and is open to influence, and possibly manipulation by incumbents.

20. Furthermore, monitoring and reporting of facility capacity and distribution is weak. There is no obligation to report back periodically by facilities on issues of major policy concern, and there is no central database, either nationally or provincially of current facilities (including types) and numbers of beds, area of distribution, and the extent of use by market players. This type of reporting is essential in the case of healthcare markets.

21. The HMI has also observed that there is no requirement that new licenses be commissioned (within a certain period), thus creating a sub-market for the sale of licenses. Further, the sale of licences or changes in ownership, do not seem to be scrutinized by the provincial departments and importantly the competition authorities. This may impact on competition (concentration) and present a distorted picture of market entry.

22. There are no requirements for review and renewal of licenses which would allow for monitoring and evaluation function to ensure continued need and maintenance of quality. Moreover, licenses are granted in perpetuity and this robs the market of a significant management tool to ensure appropriate quality care.

23. There are no conditions attached to licensing such as obligations to report on quality, occupancy, staffing capacity, management of Remunerative Work Outside the Public Service (RWOPS), etc. These are reasonable expectations of features of well-regulated healthcare markets, internationally, which currently do not exist in the South African market.

24. The rationale behind the issuing of practice numbers and practice type numbers by the Board of Health Funders (BHF) is also not entirely understood, particularly as this information is regarded to be proprietary and confidential. The HMI understands that this information is used by the funders for billing purposes, and as such, facilities without this information could be hindered from billing. This could heighten barriers to entry and lead to exclusion of market

players. The HMI does not believe that this function should be done by market players, but rather, it should be a function embedded in the licensing process.

25. The manner in which licensing applications are processed is not transparent and therefore not accessible to the public and potential new entrants. The licensing regulations are often framed so broadly that they lead to wide discretionary power exercised by the Head of Department making the decisions. This lack of transparency regarding the criteria used, was cited as a significant barrier by stakeholders. Further, the reasons for granting and/or denying licences are allegedly not clearly communicated and explained. This possibly opens the process to abuse by the deciding authority, to the detriment of potential new entrants.

26. Stakeholders also raised concerns about the duration of the licensing process. Several stakeholders stated that applying for a license, whether to develop a new facility or for extensions and amendments, is a lengthy process and can take 2-3 years and in some instances even longer. The HMI notes that the lack of clear timeframes may discourage potential new entrants.

POSSIBLE REGULATORY INTERVENTIONS

27. The HMI notes that the above regulatory failures relating to the facility licensing regime impacts on competition, entry and innovation. This may contribute to rising expenditure in the private healthcare sector, thus reducing affordability and limiting access to private healthcare services. In this respect, the HMI proposes the following interventions to address these failures of the licensing regime.

    a. A standardised, national licensing regime that must be implemented by provincial departments. The role of the provincial departments should be limited to the implementation of the prescribed standardised licensing model and applying the model to specific market dynamics in the provinces. Critical elements of an improved licensing framework include, inter alia; assessment and projections of market need per specialty, per means of delivery (inpatient, outpatient, day-care), assessment of competitive impact, and assessment of clinical impact. Incorporated in this process, should be the issuing of practice numbers and type classifications to enable monitoring and accountability.

b. A mandatory monitoring and reporting framework should be embedded in the regulations so that provinces are compelled to periodically collect data from facilities and report standardised information to the national authority to enable the latter to exercise oversight over the licensing process and market capacity. Continuation of licence agreements should be dependent on facilities meeting reporting requirements. These will require facilities to provide figures on any changes to bed allocation, levels of care and occupancy rates so that rational planning for any new facilities can take place on the basis of accurate data and projections.

c. 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. In this regard, the HMI therefore recommends that the licensing criteria encompass intrinsic incentives to encourage novel and innovative healthcare delivery models. There should be deliberate infusion of innovative systems in the accreditation requirements for licence approvals. The accreditation process should prioritise applicants that demonstrate innovative and cost-effective structures of healthcare delivery with excellent clinical outcomes over and above business-as-usual licensing requests to expand beds and capacity. Preference should also be given to underserviced areas to ensure equitable distribution of healthcare facilities.

d. 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.

e. All licensing processes including criteria applied in considering applications, and timeframes, should be published to increase transparency and enable market players and potential entrants to access relevant information. Furthermore, the licensing process should comply with the principles of administrative law.