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Dear Paulina and Mapato

PROPOSED REGULATORY INTERVENTIONS FOR LICENSING OF HEALTH FACILITIES / MEDICLINIC'S COMMENTS

We refer to the Health Market Inquiry (HMI) document entitled "Proposed Regulatory Interventions for Licensing of Health Facilities - Discussion between Health Market Inquiry, National Department of Health, Provincial Departments and Relevant Stakeholders" published on 14 February 2018 (Licensing Paper) for comment.

As a provider of private healthcare services Mediclinic Southern Africa Proprietary Limited (Mediclinic) is directly affected by the licensing regime for healthcare facilities. Mediclinic operates 49 acute care hospitals and 2 day hospitals across South Africa and a further 3 acute care hospitals in Namibia. As such, Mediclinic has exposure to all the provinces in which it operates (which excludes only the Eastern Cape) and the Namibian regime on licensing. Interestingly, in Namibia no approval is required to build or expand a hospital as these decisions are left to free market forces. The Namibian Department of Health's role is to inspect and license the facilities only prior to rendering services there, in order to determine that the facility is safe to render patient care.

1 Procedural fairness

Mediclinic notes with concern the very limited time periods afforded to stakeholders to consider the Licensing Paper and comment thereon. Mediclinic submitted detailed comments on the licensing regime as early as

October 2014, which issue again arose in the context of the 2016 public hearings. The HMI has not consulted with stakeholders on this issue in any form since then. Mediclinic then received the Licensing Paper on Thursday 15 February 2018, with the unreasonable expectation of comments having to be submitted within less than one week, on today's date. Whilst Mediclinic has prepared these comments in an effort to assist the HMI, it reserves its rights to supplement these submissions.

2 Prevailing licensing regime

2.1 Mediclinic submits comments based on its experience over more than 30 years in the private hospital industry and its interaction with the various provincial Departments of Health. This interaction follows a multiple-step process in respect of the construction of a new facility or expansion of an existing facility. In broad terms, the applicant firstly submits an application to construct or expand a facility and if this is approved (wholly or partially), building plans are submitted. Once these are approved construction can commence and, once completed and ready for commissioning, the inspection process is undertaken by the Department of Health. If the facility passes the inspection, a license certificate, valid for one year, is issued. The entire process is loosely referred to as "licensing" but this is strictly speaking not correct. In Mediclinic's experience, gathered from many applications over many years, the Western Cape functions optimally in terms of providing (a) certainty of process and transparency, and (b)clarity to applicants and other stakeholders. In contrast to this experience, Mediclinic has found in other provinces that there have been inordinate delays in the Departments dealing with applications and various cumbersome steps in the process. This has, over the years, been explained due to staff shortages, inability to arrange the necessary committee meetings, the committees not having a quorum and a myriad of similar dilemmas, such as the inability to evaluate building plans and the lack of inspection staff and finances to carry out pre-commissioning and annual inspections. This has thus, unfortunately, meant that there has been considerable uncertainty and delays in managing multi-million rand investments, delays in providing much-needed patient care and also several court cases against the provincial Departments of Health based on administrative shortcomings. Mediclinic does not wish to raise criticisms against the provinces, but urges the HMI to consult with and consider the Western Cape Department's processes to view an existing well-functioning system, from which the others could learn.

2.2 There are certain statements or suggestions contained in the Licensing Paper which require comment in order to correctly reflect the licensing regime and/or to convey Mediclinic's views on the matter.

2.3 We note that the "*HMI has 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*"[1]. The Western Cape regulations do, in fact, provide a timeframe within which building plans must be submitted and that once these are approved, uninterrupted construction of the facility must commence. The time frame until opening may, of course, take a few weeks for minor alternations or a few years should a new fully fledged acute hospital be built. To determine the commissioning date would thus be difficult, but rather a continuous uninterrupted process

[1] Licensing Paper, paragraph 21.

must be followed. In Mediclinic's experience the Provinces that rely on Regulation 158 of the Health Act of 1977 (R158) also have the power to place conditions on the approval to construct or alter a facility and determine, for example, timeframes for the submission of building plans and the commencement of construction. This particular point was established in litigation based on administrative law against a provincial Department of Health, wherein the approval to construct or enlarge a facility carried conditions. This is entirely acceptable in law in terms of the prevailing regulations. Mediclinic has, over the years, been approached by individuals and businesses who have suggested that they have approvals (incorrectly referred to as "licenses") for sale. In each of these cases this was not related to a lack of timeframe to develop the facility, but an inability to raise the necessary capital to construct a new facility. The construction of a new facility is extremely expensive. As guidance in terms of building costs, press articles advise that the then-new 270 bed Mitchell's Plain hospital, which opened in 2013, took three years to build at a cost of R553million, with an additional R99millon spent on equipment[2]. The Northern Cape is also about to open a mental healthcare facility and the press advises that the construction costs amount to R1.86bilion[3]. In Mediclinic's experience many individuals and businesses have over the years applied for and received approvals to construct facilities, but are then unable to proceed due to an inability to access the high capital input that is required, particularly in an environment where the successful applicant is unable to provide security for the debt.

2.4 The Licensing Paper further reflects that "*there are no requirements for the review and renewal of annual licenses*", that these are granted "*in perpetuity*" and that this "*robs the market of a significant management tool to ensure appropriate quality care*"[4]. The observations of the HMI are not accurate. Once a new facility or an expansion of an existing facility is ready for commissioning, it is inspected in detail by the respective provincial Department of Health. In Mediclinic's experience these inspections are thorough and focus on ensuring that a safe environment exists to render patient care. In many instances the individual hospitals have been required to make alterations (e.g. moving hand wash basins and changing fire doors) before the license certificate is issued and the hospital can admit patients. The license that is issued is only valid for a particular calendar year and is only re-issued after a successful annual inspection undertaken by the Department. The license is not renewed if there are concerns and the Departments provide details of changes required and issue notices of non-compliance where needed. The license is thus not granted "in perpetuity" and strict inspection compliance has to be met. At the annual inspections the inspection team has access to patients, patient records, and any information which they wish to view, thus also undertaking a clinical review. The clinical review will be further enhanced by the Office of Health Standards Compliance which has recently published its Norms and Standards to be used in their inspections.

2.5 In providing examples as to the type of conditions that could be attached to licensing the HMI suggests "management of Remuneration of Work Outside the Public Service (RWOPS)".[5] The topic of RWOPS needs careful consideration as to whose responsibility and, more so, ability it is to manage healthcare

[2] iol news, 27 June 2013.
[3] Timeslive, 6 February 2018.
[4] Licensing Paper, paragraph 22.
[5] Ibid, paragraph 23.

workers who are employed by the public sector, their specific contractual responsibilities to the public sector and the extent of their approval to work in the private sector. Mediclinic does not support unauthorised RWOPS but is not in a position to determine the employment contract of each public sector employee, their individual compliance thereto and in fact even measure their time spent in the private sector. There are no management tools or processes to enable measurement of non-employees and Mediclinic suggests that the measure should be done by the public sector place of employment to ensure that the individual concerned is rendering the time and tasks due as determined by the contract of employment at the place of employment.

2.6 The HMI notes that "*the manner in which licensing applications are processed is not transparent and therefore not accessible to the public and potential new entrants*"[6].The level of transparency and accessibility varies between provinces, again with the Western Cape Department of Health having a very transparent and accessible system. Some of the other provinces have attempted to emulate this process, with varying levels of success. In the Western Cape the applications are advertised in the local press and are available for inspection so that any interested parties can submit comments on the application. The process is clearly set out in the regulations and is accessible to any interested person. The process in the Western Cape similarly spells out very clear timeframes, contrary to the HMI general comment in this regard[7].

3 Impact of regulation on innovation

3.1 The Licensing Paper alleges that there is a lack of coordination between regulatory bodies who are relevant in accrediting different players and health establishments who wish to collaborate to offer innovative forms of care.[8] The Health Professions Council of South Africa (HPCSA) and the Council for Medical Schemes (CMS) are specifically mentioned. The Licensing Paper makes a recommendation regarding coordination between regulatory bodies to reduce fragmentation in licensing and accreditation.[9] It is agreed that coordination is beneficial, however this statement lacks context and therefore it is not clear from the document why coordination between these specific organisations are required.

3.2 Mediclinic's previous submissions to the HMI have highlighted the dampening effect that HPCSA ethical rules and medical scheme regulations have on innovation in both the delivery and funding of private healthcare[10]. HPCSA Rules prevent joint billing by hospitals and doctors and the reimbursement of providers on the basis of 'global fees', thereby stifling innovative integrated delivery and billing models which aim to reduce fragmentation, enhance clinical care and reduce healthcare costs. In addition, the fact that private hospitals generally cannot employ doctors makes it difficult to align incentives between hospital and doctor to promote efficient care across the care continuum, to improve the healthcare value proposition

[6] Ibid, paragraph 25.
[7] Ibid, paragraph 26.
[8] Ibid, paragraph 18.
[9] Ibid, paragraph 27d.
[10] Mediclinic's submissions in response to the call for submissions dated 1 August 2014, paragraphs 2.5.4.4.3, 4.11, 4.17.5, 4.19.3 and 4.19.4.

and to jointly develop new innovative low cost hospital models. Medical scheme regulation also does not allow for integration between schemes and providers, hence prohibiting vertically integrated models such as Health Maintenance Organisations (HMO). These types of organisations were enabled under the repealed Medical Scheme's Act of No. 72 of 1967 but are not allowed for in the current regulation, i.e. the Medical Scheme's Act of 1998.

3.3 Coordination between the regulatory bodies will not bring about innovation in the delivery of healthcare if the development of innovative products and healthcare models remains stifled by the aforementioned aspects of private healthcare regulation. Over-regulation, which serves to heighten barriers to entry, should be guarded against.

3.4 Furthermore, it is not clear from the document what the HMI envisions the role of the CMS to be in addressing the "*regulatory fragmentation in licensing and accreditation of different health establishments*"[11]. A more detailed explanation of the proposal is required from the HMI before appropriate comments can be submitted.

3.5 The HMI proposes that the licensing criteria encompass intrinsic incentives to encourage novel and innovative healthcare delivery models.[12] In this regard, it is not the licensing regulation but rather the regulation preventing integration between healthcare providers that is the main regulatory obstacle in the development of innovative healthcare delivery models.

3.6 The Licensing Paper does not outline proposals as to how the licensing authority would measure or assess that a model is innovative or cost effective. If innovative and cost effective models are to be favoured then the cost of delivering healthcare by the various types of private sector providers must be researched and understood by the HMI and the bodies who will be assessing and approving the licensing applications.

4 Licensing, accreditation and billing

4.1 The role of the OHSC is not accurately outlined in the HMI's document and is thus unclear in the context of the proposals set out by the HMI. The document 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*"[13] and therefore makes the assertion that that there should be some streamlining between the OHSC and other regulatory bodies.

4.2 The OHSC is, currently and under the proposed NHI system, to provide certification of compliance. The core function of the OHSC is therefore to monitor and enforce compliance with the Norms and Standards Regulations which were finalised and published in January 2018. This includes carrying out inspections and certifying that a health establishment is compliant or non-compliant with the norms and standards. The

[11] Licensing Paper, page 8, paragraph 27d.
[12] Ibid, paragraph 27c.
[13] Ibid, paragraph 27d.

National Health Insurance Policy document dated 30 June 2017 (NHI White Paper) states the following regarding the OHSC's role under the proposed NHI system:

"The accreditation process will require providers to firstly meet the minimum quality norms and standards and be certified by the OHSC, and where relevant by the appropriate statutory professional council, which will continue to register and license professionals in line with national health legislation.

Accreditation by the NHI Fund will be based on the health needs of the population and will require provider compliance with specific information and performance criteria."[14]

4.3 It is clear from the extract above that OHSC certification will be a component of the accreditation process and the OHSC will not be the regulatory body responsible for "licensing and accreditation" as stated in the HMI's document. For the OHSC to be the body responsible for inspecting, licensing and accreditation of healthcare facilities, as well as the custodian of data on quality and standards, would be unacceptable in terms of principles of good governance. These tasks should be separated.

4.4 The HMI raises concerns about the Board of Healthcare Funders (BHF) issuing practice numbers and proposes that this function be embedded in the licensing process. It is agreed that an inefficient system of allocating practice numbers would hinder facilities from billing however the rationale for incorporating the issuing of practice numbers into the licensing process is not clear. Medical schemes may only reimburse healthcare providers who have a valid practice number. Historically, the issuing of practice numbers was inherited from the time when the Representative Association of Medical Schemes (RAMS), which is now the BHF, was the representative body for the medical schemes. The BHF, via the Practice Code Numbering System, issues practice numbers to doctor or group practices, pharmacies, facilities, etc. who are registered with the HPCSA or have a valid licence to operate the respective facility. The healthcare provider however does not require a practice number in order to be registered or licensed with the respective authorities. Practice numbers are therefore not only used to identify licensed facilities but rather a mechanism in the market which signals to schemes that a healthcare provider is licensed or registered to deliver healthcare services. The practice code system also provides the scheme with a flag of the type of healthcare facility or provider, enabling the scheme to determine which types of services the relevant provider can be reimbursed for. The organisation who manages this function should do so for all healthcare providers including pharmacies, doctor practices and other types of healthcare service providers. There should also be coordination between the issuing body, healthcare funders and providers to ensure that there is transparency around the process and allocation of practice numbers. The mandate of this body would therefore go beyond licensing of facilities and Mediclinic would caution against incorporating this function into the licensing framework.

[14] National Department of Health. National Health Insurance Policy (White Paper) 30 June 2017, paragraphs 279 and 280.

5 Recommendations regarding licensing health establishments in the context of NHI

5.1 Mediclinic would caution against possible recommendations which are dependent upon the current NHI policy documents. The NHI white paper envisages the implementation of an NHI system over a 14 year period. A variety of legislative reforms and consultative engagements will be necessary prior to the full implementation of NHI by 2026 (at the earliest). These numerous tasks are alluded to within the "NHI Implementation: Institutions, bodies and commissions that must be established" document.[15]

5.2 In light of policy uncertainty (which policy itself is of a long-term nature) and in the absence of a promulgated bill, it is premature to make recommendations based on NHI in its current format. Importantly, the exact nature, design and feasibility of the proposed NHI system are still under discussion.

5.3 Mediclinic would again like to draw attention to numerous prominent documents such as the Davis Tax Committee: Report on Financing a National Health Insurance for South Africa and the Report of the High Level Panel: on the Assessment of Key Legislation and The Acceleration of Fundamental Change. These documents highlight some fundamental concerns and features of the NHI system in its current format which are still to be clarified. These features are diverse and include, among other things, the depth and breadth of coverage, the financing, and healthcare delivery mechanisms.

5.4 Without a clearly articulated benefit package and services offered, as well as the accompanying healthcare provider delivery mechanism it is unclear the role that private healthcare establishments will perform in the envisaged NHI structure.

6 Need versus Demand

6.1 Reference is made throughout the HMI's Proposed Regulatory Interventions for licensing of Healthcare Facilities that licensing should be dependent on need. By its very nature, private provision of healthcare services is bound by the dynamics of a given set of fiduciary mandates and market dynamics. In this context, the notion of "need" must be carefully applied, need is a component of demand and not distinct from it.

6.2 The application of the concept of need, without due consideration for the level of demand for the licensing of private healthcare establishments is problematic. While there are fundamental differences between the terms "demand" and "need", the former remains inextricably bound to the latter. The purpose of this section is to provide an interpretation of the concepts as well as the relationship of these concepts to the notion of shortage.

6.3 While in principle there are no difficulties with these concepts, in practice there can be; particularly as it pertains to the capacity of private health establishments to render these services within the bounds of their respective set of fiduciary mandates and market dynamics. This must also be understood within the context

[15] National Department of Health. 2017. NHI Implementation: Institutions, bodies and commissions that must be established available at: http://www.health.gov.za/index.php/component/phocadownload/category/383.

of the South African healthcare landscape and the capacity of private providers to render high quality acute care services to patients' whose healthcare needs have traditionally been financed through the general fiscus by public facilities under the budgetary ambit of the public healthcare system. Currently there is no mechanism to allow for private providers to be reimbursed for the delivery of healthcare to indigent patients.

6.4 The "need" for the provision of healthcare establishments is a normative judgement based on what the members of a given population ought to receive. A populations' healthcare need can be defined as "*that quantity of medical services which expert medical opinion believes ought to be consumed over a relevant time period in order for its members to remain or become as "healthy" as is permitted by existing medical knowledge*."[16]

6.5 With respect to the knowledge on the state of the populations' health need it is worthwhile noting that there are several difficulties in accurately defining the level of need. An accurate specification of need for medical services requires:

6.5.1 perfect knowledge on the state of the populations' health;

6.5.2 a clearly defined status of what constitutes "good health"; and

6.5.3 a perfect knowledge on what medical care can do to improve ill health.

6.6 Need, however, "*is only one factor affecting demand for care; basing resource allocations solely on medical need will result in a misallocation. If the estimated quantity required to meet medical need exceeds the quantity that people will actually use, then there will be an under-utilisation of hospitals and physicians, resources that could have been used elsewhere or in another manner. If, on the other hand, people demand more medical care than would be provided solely on the need criterion, then there will be excess demand and waiting times…thus planning on need is likely to result in either too few or too many resources*."[17]

6.7 Private medical scheme coverage remains an important determinant of demand for private healthcare utilisation. This is because no significant financial subsidies or funding channel is afforded to private providers for the delivery of services to the poor and indigent consumer base. Accordingly, private health establishments must rely on the incumbent degree of medical scheme coverage to render their services.

6.8 In line with utilising medical scheme coverage as a benchmark for demand, various other indicators are used to establish the effective utilisation of private health establishments. Insofar as Mediclinic is concerned, private healthcare establishments are developed where fiduciary mandates and market dynamics deem it appropriate.

6.9 The establishment of private health facilities in urban metropolitan areas also provides the added benefit of a high concentration of potential consumers. Given the significant underlying fixed costs of providing high

[16] Jeffers, J., et. Al. 1971. "On The Demand Versus Need For Medical Services And The Concept Of "Shortage" *American Journal of Public Health, 61 (1),* January 1971.
[17] Same as above.

quality acute care services and the highly specialised nature of the service rendered it is essential that facilities are established in areas where there are a significant number of consumers to ensure the economies of scale and revenue to sustain the establishment. While this results is a burden of travel for certain patients, it is practically and financially impossible to establish a high quality acute care facility in close proximity to all prospective users who are willing and able to procure these services; to do so would render the service either financially unaffordable to procure or financially unfeasible to render. In addition, in order for a health facility to function it requires health care professionals who reside in close proximity to the facility. This is particularly true for doctors who regularly need to visit patients during the night when they are not present at the hospital or their consulting rooms which are generally in close proximity to the hospital, and to be nearby to patients in case of emergencies. If sufficient doctors and nurses do not reside in the underserviced areas, the facility will not be feasible. Appropriate caseloads are necessary for financial justification of a healthcare facility but are also an important feature for ensuring the achievement of good clinical outcomes. In light of the above, the recommendation that "*preference should be given to underserviced areas to ensure equitable distribution of healthcare facilities*" should be tempered given the aforementioned requirements for adequate caseloads and economies of scale.[18]

7 Possible regulatory interventions

7.1 Mediclinic submits the following comments and recommendations in respect of the possible regulatory interventions proposed by the HMI:

7.1.1 The HMI proposes "*A standard, national licensing regime that must be implemented by provincial departments*", including elements (amongst others) of "*market need per speciality*", "*competitive impact*" and "*clinical impact*" and "*issuing of practice numbers*"[19]

7.1.1.1 As set out above the HMI is urged to consider the Western Cape regulations which, in Mediclinic's view, are transparent, provide clarity and are well functioning. Mediclinic is of the view that the assessment of competitive impact is not within the proper scope, functions or abilities of the health authorities and the extent of the competition and economic expertise that is required for a robust assessment would need to duplicate the knowledge and expertise of the Competition Commission and would not be feasible. In addition, the assessment of clinical impact is not measurable at the stage where approval is required to construct a multi-million rand facility, but only once services are actually rendered. The measurement of these services is to be undertaken by the OHSC and a duplication of the services by the licensing authority would mean a duplication of tasks and costs.

7.1.1.2 The practice code number system is relevant to all healthcare providers, including facilities, doctors rooms, registered healthcare practitioners, pharmacies, etc. who wish to be reimbursed by medical schemes. This is therefore not only relevant to facilities and Mediclinic would therefore caution against embedding this function into the licensing regime for facilities

[18] Mediclinic's submissions in response to the HMI call for submissions dated 1 August 2014, page 8.
[19] Licensing Paper, paragraph 27a.

7.1.2 Mandatory monitoring and reporting on "*bed allocation, levels of care and occupancy rates*" in order to guide "*rational planning for any new facilities*"[20] is proposed.

7.1.2.1 The general principles proposed appear sound but the actual details on measurables would need critical analysis to ensure that they are feasible, practical and rationally determine how the measures and reports are used to determine decision making. By way of example, in the current application evaluation process the various departments of health consider factors such as the number of beds in the public sector, although these serve a different market to the private sector and, in Mediclinic's submission, should not be a factor in decision making. Similarly, by way of example, an application for ICU beds for a cardiac unit should not be measured against available ICU beds that are used to care for general ICU patients.

7.1.2.2 The collection of data from facilities also needs to bear in mind the protection of business sensitive and confidential information and, depending on the systems developed (which then need to be implemented in a uniform manner), could be expensive. A good, efficient system thus needs to be established that does not provide for any variance in data results and analysis.

7.1.3 The HMI proposes that "*The licensing regime should give preference to new, improved and innovative models of care*", "*the accreditation process should prioritise applicants that demonstrate innovative and cost effective structures…with excellent clinical outcomes*"[21].

As set out herein, Mediclinic is of the view that innovation in healthcare is curtailed by restrictive regulatory rules such as the HPCSA ethical rules, and not by the licensing regime. The effectiveness of an innovative model as well as the cost effectiveness thereof (as well as the clinical outcomes) would not be measurable at the time of applying to establish a new facility and this data would only be available after a certain period of time of actually operating the facility. It is thus submitted that these criteria are practically not feasible and, in respect of the effectiveness of the innovation and its actual cost-effectiveness would be a normal business risk for the applicant. At the same time, there has been no published study by the HMI as to the underlying costs of the private sector and as such there is no guideline or framework to determine what would be considered to be "cost effective". Cost effectiveness is also subject to market forces beyond the control of the facility, such as Eskom cuts and the drought in the Western Cape, both of which required extensive and costly investment in generators, boreholes and water treatment plants. In addition, innovation metrics are notoriously complex and would need extensive business analysis and a benchmark to assess feasibility. This would be expensive and beyond the realm of the Department of Health's functions.

7.1.4 It is proposed that *"….under NHI the OHSC will be the responsible body for licensing and accreditation*.[22]"

[20] Ibid, paragraph 27b.
[21] Ibid, paragraph 27c.
[22] Ibid, paragraph 27d.

7.1.4.1 The tasks of the OHSC are clearly covered in the prevailing regulatory framework. Mediclinic does not view the task of the OHSC to "licence" facilities as currently undertaken by the provincial Departments of Health. It is agreed that streamlining between the different bodies is essential – there should however be a clear separation of powers and authority while at the same time ensuring that there is no duplication of tasks.

7.1.4.2 In light of policy uncertainty and in the absence of a promulgated bill, it is premature to make recommendations based on NHI in its current format. Mediclinic would caution against proposals which are based on the current NHI policy documents.

7.1.5 "*Licensing processes…should be published to increase transparency*…[23]"

Mediclinic agrees that the process should be transparent and comply with administrative law. However, should the approval process favour innovative and cost effective business models as suggested[24], careful consideration needs to be given to the business sensitive and confidential information (which, in the case of an innovative business model could favour robust competition) and how this would be protected. The process can only be transparent and available for scrutiny by the public and other stakeholders and competitors where is does not harm the intellectual capital of the applicant.

Mediclinic looks forward to meaningful engagement on these issues. Please provide us with more details regarding the proposed discussions with stakeholders.

Yours faithfully

ANDRE DE LANGE / SUSAN MEYER
CLIFFE DEKKER HOFMEYR INC

[23] Licensing Paper, paragraph 27e.
[24] Ibid, paragraph 27c.