**IN THE HIGH COURT OF SOUTH AFRICA,**
**FREE STATE DIVISION, BLOEMFONTEIN**

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| **Reportable:** | **YES/NO** |
| **Of Interest to other Judges:** | **YES/NO** |
| **Circulate to Magistrates:** | **YES/NO** |

Appeal No.: A45/2015

In the appeal between:-

**THE HOSPITAL ASSOCIATION OF SOUTH AFRICA NPC** Applicant

and

**THE MEC OF HEALTH FOR THE FREE STATE PROVINCE** Respondent

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**CORAM:** MOLEMELA, JP *et* MUSI, J *et* DAFFUE, J

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**JUDGMENT BY:** MOLEMELA, JP

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**HEARD ON:** 25 JULY 2016

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**DELIVERED ON:** 22 DECEMBER 2016

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*Introduction*

[1] This is an application brought by the applicant, the Hospital Association of South Africa NPC ("HASA"), to review and set aside the decision of the respondent, the Member of the Executive Council of Health of the Free State Province ("the MEC") to promulgate the Regulations Governing Private Health Establishment No 78 of 2014 ("the Regulations").

[2] The Regulations referred to above were promulgated in terms of the Free State Hospitals Act 13 of 1986[1] ("the Hospitals Act"), which empowers the Member of the Executive Council for Health ("MEC") to establish, maintain and manage provincial hospitals and to regulate, restrict or prohibit the establishment of private hospitals and other private healthcare establishments.

[3] Prior to 9 September 2014, the regulations that were in operation were the Regulations Governing Private Hospitals and Unattached Operating Theatre Units (as amended) Regulation R158 of 1 February 1980 ("the 1980 Regulations"). On 9 September 2014, regulations were published in a Provincial Gazette ("the 2014 Regulations"), which repealed and replaced the 1980 Regulations. These are the regulations which gave rise to the dispute under consideration.

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[1] This is in terms of Section 16(1)(i) of the Free State Hospitals Act 13 0f 1996, which provides:-

*"16 (1) The responsible Member may make regulations with regard to-*

*(a) .....*
*(b) .....*
*(c) .....*
*(d) .....*
*(e) .....*
*(f) .....*
*(g) .....*
*(h) .....*
*(i) private hospitals, nursing homes, maternity homes or other similar institutions where nursing is carried on for the benefit of patients accommodated therein and where fees are charged by the owner or lessee of any such hospital, home or institution in respect of nursing services rendered to such patients or where contributions are made by such patients towards the cost of such services-*

- *(i) regulating, restricting or prohibiting the establishment or running of such hospitals, homes or institutions;*
- *(ii) prescribing minimum standards with which such hospitals, homes or institutions shall comply;*
- *(iii) relating to the registration and inspection of such hospitals, homes or institutions;*
- *(iv) prescribing the fees to be paid, the registers to be kept, the certificates to be issued and any other requirements to be complied with in connection with the registration of such places;*
- *(v) relating to patients who may be accommodated therein;*
- *(vi) relating to the registration of persons in charge of such hospitals, homes or institutions, and the furnishing of returns or particulars of patients admitted thereto and persons employed therein; and*
- *(vii) providing for the refusal to register, or the removal from the appropriate register of, any such hospital, home or institution which the responsible Member or any specified person or class of person may consider unsatisfactory on specified grounds;"*

[4] HASA attacks the procedure followed by the MEC leading to the publishing of the regulations. It contends that the promulgation of the 2014 Regulations was not preceded by any meaningful consultation process. It avers that the 2014 Regulations are convoluted, poorly drafted and introduce sweeping changes to the manner in which private hospitals and other private health establishments are established and regulated in the Free State Province.

[5] HASA further contends that several provisions of the 2014 Regulations are cast in impermissibly vague terms. It also alleges that the regulations will have a chilling effect on the creation and extension of private hospitals and other health establishments in the province, restricting patients' rights to access health care services. It argues that the regulations in effect require private hospitals to compensate for deficiencies in the state healthcare system in order to be registered or licenced. HASA seeks an order reviewing and setting aside the 2014 Regulations in their entirety on the basis that they are unlawful, irrational and unreasonable. The order sought is hinged on the application of the principle of legality on account of their vagueness and on the provisions of the Promotion of Access to Justice Act (PAJA).

[6] The MEC asserts that the procedure followed by its officials was fair, as the regulations were preceded by two notice-and-comment periods. The MEC maintains that none of the regulations are impermissibly vague. He also denies that Regulation 14 imposes impermissible public obligations on private hospitals.

*The nature of the review application*

[7] It must be pointed out from the outset that the relief sought by the applicant in its review application is for "the setting aside of the decision of the respondent, the MEC of Health for the Free State Province ("the MEC") to promulgate the

Regulations Governing Private Health Establishments No 78 of 2014." The nature of the relief sought as set out in the Notice of Motion was never amended. The MEC is empowered to make regulations in terms of section 16[2] of the Free State Hospitals Act. This power is not in conflict with any national legislation. There is thus no legal impediment that precludes the MEC from publishing any regulations.

[8] It is evident from HASA's Heads of Argument that its attack is directed at the regulations on account of their vagueness and that it does not question the power to promulgate the regulations. In its Answering Affidavit, the MEC introduced its opposition of the review application as follows: "I have read the founding papers. The purpose of this affidavit is to set out the grounds upon which I oppose the application to review and set aside the final regulations." It is evident from the tenor of the entire Answering Affidavit that the MEC did not understand the dispute to be confined to determining whether the MEC has the power to promulgate regulations or not, but rather as seeking the setting aside of the regulations on account of their alleged vagueness or their onerous nature.

[9] Given the nature of the dispute, pertaining as it is to regulations intended to regulate healthcare, and the fact that there is no prejudice to the MEC, it is in the interests of justice that substance be put over form, and that the dispute be adjudicated upon notwithstanding the flaws pertaining to its categorisation. The conclusion that there is no prejudice to the MEC is based on the fact that the MEC did not raise any objections relating to the relief sought. It is also clear from the MEC's averments that he understood the dispute to be about the validity of the 2014 Regulations and not about the power of the MEC to promulgate them. That this is the case the MEC indeed came to meet is also borne out by the fact that the MEC proffered that if this court were to find that HASA's objections pertaining to specific provisions of the 2014 regulations

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[2] See footnote 1 *supra.*

have merit, then the appropriate remedy would be to set aside those specific regulations and not the regulations as a whole. There is therefore sufficient basis to adjudicate the dispute.

*The issues to be decided*

[10] The issues to be decided are, firstly, whether the process leading to the 2014 Regulations was procedurally fair and, secondly, whether such regulations are rational, reasonable and lawful.

*Locus Standi*

[11] HASA indicated in its papers that it is bringing this application in its own interest, the public interest and the interests of its members. The MEC accepts that HASA has the right to challenge the legality of the regulations "on grounds that apply to it or on objective grounds" but disputes its right to direct such a challenge on behalf of its members. According to the MEC, "if a HASA member believes that its representations were not considered, then it is the HASA member that must apply to review and set aside the regulations."

[12] In *Ferreira v Levin NO; Vryenhoek v Powell NO*[3], O'Regan J stated that the relief sought in public law cases in the new Constitution era *'is generally forward-looking and general in its application, so that it may directly affect a wide range of people"* In *Kruger v President of the Republic of South Africa*[4] the court held that where significant legal uncertainty exists, the need for legal certainty could provide sufficient interest for standing where the legislative regime in question was of *"direct and central importance"* to the field in which the litigant practiced and where it undermined the administration of justice. More recently, in *Genesis Medical Scheme v Minister of Health (Medi-Clinic Southern Africa (Pty) Ltd and others as applicants to intervene; Treatment*

[3] 1996 (1) SA 984 (CC).
[4] 2009 (1) SA 417 (CC).

*Action Campaign NPC and others as amici curiae)*[5]*,* HASA applied for, and was granted, leave to intervene as a respondent. The main application concerned the interpretation and application of the provisions of the Medical Schemes Act and regulations. HASA's standing to intervene was based on its having a direct and substantial interest in the relief sought in the main application. HASA was able to intervene without its members having to take part individually.

[13] In light of the authorities mentioned in the preceding paragraph, I am persuaded that HASA has established a basis for challenging the legality of the 2014 Regulations not only in its own interest but also on behalf of its members. It therefore has the requisite *locus standi*.

*Procedural Fairness*

[14] During the hearing of the application, this court was referred to the Record of the Decision. It is evident that draft regulations were put out for comment on 29 June 2012. It would appear that only two private bodies submitted representation on the draft. Some changes were made to the draft and on 18 July 2014 the revised draft regulations were published with a notice calling for comments. Seven organisations made comments on the 2014 draft regulations. The regulations under consideration were thereafter promulgated. Although HASA attacked procedural fairness on various grounds, it states in its Heads of Argument that it persists in its procedural unfairness challenge to the 2014 Regulations only to the following extent: that the regulations were published following a perfunctory and inadequate public comment process in circumstances where the MEC failed to pay any heed to the substance of the comments received from HASA and its members, resulting in the promulgation of regulations that are riddled with the very same errors that were identified in submissions made to the MEC prior to their promulgation.

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5 [2015] 4 All SA 302 (WCC).

[15] It is established law that the question whether a fair procedure is followed depends on the circumstances of each case.[6] HASA could not refute the MEC's contention that some of the comments made by its members in the second notice period were subsequently adopted and incorporated into the regulations. The fact that some of HASA's concerns were not accommodated should not, without more, lead to a conclusion that such concerns were not considered. This view is buttressed by the following remarks made by Chaskalson CJ in *Minister of Health and Another NO v New Clicks South Africa (Pty) Ltd & Others* are apposite[7]:

> *"As Lord Mustill points out, "the principles of fairness are not to be applied by rote identically in every situation." It cannot be expected of the lawmaker that a personal hearing will be given to every individual who claims to be affected by regulations that are being made. What is necessary is that the nature of the concerns of different sectors of the public should be communicated to the law-maker and taken into account in formulating the regulations. …Where laws are made through legislative administrative action, the procedure of publishing draft regulations for comment serves this purpose. It enables people who will be affected by the proposals to make representations to the law-maker, so that those concerns can be taken into account in deciding whether or not changes need to be made to the draft."*

[16] With regards to HASA's argument that Regulation 14 ought not to be included in the 2014 before regulations envisaged in the National Health Act[8] have been promulgated, I accept that Regulation 14 is in many respects similar to section 36 of the National Health Act. I am, however, of the view that the fact that the regulations envisaged in the National Health Act have not yet been promulgated does not preclude the inclusion of Regulation 14 in the 2014

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6 Minister of Education, Western Cape and Another v Beauvallon Secondary School and Others 2015 (2) SA 154 (SCA) at para [19].
7 2006 (2) SA 311 (CC) at 381E-I.
8 Act 61 of 2003

Regulations.[9] I am satisfied that HASA's attack on procedural fairness therefore lacks merit and ought to be dismissed

*Are the impugned regulations vague?*

[17] HASA has in its Founding Affidavit repeatedly described various provisions of the regulations as vague, including Regulation 14 as being so vague as to offend the principle of legality. The MEC vehemently denies this allegation. The text of the impugned 2014 Regulations warrants scrutiny to determine whether they are indeed vague. It must be borne in mind that the impugned provisions of the 2014 regulations must not be considered in isolation but rather in the context of the 2014 regulations in their entirety. Before embarking on the process of scrutinizing the impugned regulations to determine whether they are indeed impermissibly vague as asserted by HASA, it is apt to first address myself to the principle of legality.

*Principle of legality*

[18] The principle of legality dictates that power should have a source in law and is thus applicable whenever public power is exercised[10]. In *Affordable Medicines Trust and Others v Minister of Health and Others*[11], Ngcobo J aptly stated as follows:-

> *"Regulation 18(5) was challenged on the basis that it is vague and does not conform to the principle of legality. The doctrine of vagueness is one of the principles of common law that was developed by courts to regulate the exercise of public power. As pointed out previously, the exercise of public power is now regulated by the Constitution which is the supreme law. The doctrine of vagueness is founded on the rule of law, which, as pointed out earlier, is a foundational value of our constitutional democracy. It requires that laws must be written in a clear and accessible manner. What is required is reasonable certainty and not perfect lucidity. The doctrine of vagueness does not require absolute certainty of laws.* ***The law must***

[9] See Minister of Health and Another NO v New Clicks South Africa (Pty) Ltd 2006 (2) SA 311 CC at para [146].
[10] AAA Investments (Pty) Ltd v Micro Finance Regulatory Council and Another 2007 (1) SA 343 (CC).
[11] 2006 (3) SA 247 (CC) at para 108.

> ***indicate with reasonable certainty to those who are bound by it what is required of them so that they may regulate their conduct accordingly.****The doctrine of vagueness must recognise the role of government to further legitimate social and economic objectives and should not be used unduly to impede or prevent the furtherance of such objectives."* (My emphasis.)

[19] I am of the view that the tools of interpretation laid down in a plethora of authorities will be useful in assessing whether the impugned regulations are impermissibly vague[12]. For purposes of providing historical context, I will highlight the salient features of the forerunner of the 2014 (1980 Regulations). It is, of course, also necessary to consider other provisions of the 2014 Regulations, as this will ensure that the impugned provisions are considered in proper context.

[20] The 1980 Regulations principally catered for two distinct procedures. First, there was a distinct procedure for obtaining written approval from the Head of Department of the Free State Department of Health ("HOD") for the establishment of private hospitals or alterations to existing private hospitals. In terms of these regulations, any person seeking to establish a private hospital had to apply to the HOD for written permission to do so. Once permission was received, the applicant would have to submit further forms and building plans for the HOD's approval. Any alteration or extension of a private hospital also required the HOD's written approval. Second, all existing private hospitals required a certificate of registration, issued by the HOD; these certificates of registration expired on 31 December of each year. Certificates of registration were issued if a hospital complied with the formal requirements specified in Regulation 4, requiring the suitability and safety of the premises, staff and services provided.

[21] I now consider the text of the impugned provisions of the 2014 Regulations. Regulation 3 provides as follows:-

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[12] *Natal Joint Municipality Pension Fund v Endumeni Municipality* 2012 (4) SA 593 (SCA) at para 17-26

*"3. Registration requirements of a private health establishment*

*(1) A person may not:-*

*(a) Erect, establish, maintain, manage or control a health establishment; or*

*(b) Render or permit to be rendered, a service in a private health establishment; or*

*(c) Establish, maintain, control or manage Step Down Facility, Rehabilitation Facility, Dialysis Unit; or*

*(d) Extend or alter a private health establishment or the service or services rendered in that establishment,*

*Unless, such person's application in terms of subregulations (a), (b) or (c) has been approved and registered in the Register for Private Health Establishments as contemplated in Regulations 16(4) and 17(7) and a licence has been issued in terms of Regulation 21(3)."*

*(2)*

*(3) … valid for one calendar year."*

[22] Regulation 4 stipulates as follows:-

*"4. Application for registration of licence*

*(1) A person who wishes to obtain the registration of a private health establishment and the concomitant licence or the amendment thereof contemplated by Regulation 3, must submit to the Head of Department an application on the appropriate form prescribed in Annexure "A", together with the prescribed supporting documents.*

*(2) An application must be an original, which must be hand delivered or mailed to the Office of the Head of Department.*

*(3) An applicant may withdraw the application at any time, and the Department is not liable for any costs incurred by the applicant."*

[23] Regulation 14(1) provides as follows:

*"14(1) When considering an application in order to determine whether there is a need for the proposed private health establishment, the committee may take into account the following:-*

*(i) the need to ensure consistency of health service development in terms of provincial and municipal planning;*

*(ii) the need to promote equitable distribution and rationalisation of health services, with a view to correcting inequities based on racial, gender, economic and geographical factors;*

*(iii) the need to promote an appropriate mix of public and private health care services with a view to the demographic and epidemiological characteristics of the populations to be served, the total and target population in the area, their ages and gender composition, their morbidity and mortality profiles;*

*(iv) the bed-to-population ratios and public-to-private bed ratios in the establishment's feeder areas and in the surrounding health district, region and province;*

*(v) the availability of alternative sources of health care;*

*(vi) the need to promote high-quality services which are accessible, affordable, cost-effective and safe;*

*(vii) the need to protect or advance persons or categories of persons designated in terms of Employment Equity Act, 1998 (Act No 55 of 1998) and the emerging small, medium and micro-enterprise sector;*

*(viii) the potential benefits of training and development with a view to the improvement of health service delivery;*

*(ix) the probability of the financial sustainability of the health establishment or health agency; and*

*(x) the need to ensure the availability and appropriate utilisation of human resources and health technology."*

[24] Regulation 21 provides as follows:-

*"21(1) Once a private health establishment for which approval has been granted in terms of these Regulations has been finally constructed, the applicant must within 30 days of such completion, request the Head of Department in writing to inspect by a duly authorised inspecting officer; the establishment in order to establish that it meets with the specifications set out in Annexure "B".*

*(2) The building may not be occupied before an inspection is done.*

*(3) If the Head of Department is satisfied that a private health establishment contemplated by subregulation (1) meets with the specifications set out in*

*Annexure "B", the Head of Department must issue to the applicant a licence for the private health establishment."*

[25] Even though the establishment of hospitals has been regulated for quite some time[13], it is evident from the text of the 2014 Regulations that they introduce a new procedure. In terms of Regulation 3(1) of the 2014 Regulations, a private healthcare establishment must be registered on the register for private health establishments. An application for registration will first be considered by an Advisory Committee.[14] The Advisory Committee must then make a recommendation to the HOD, who takes the final decision on the application after considering the Advisory Committee's recommendation. If satisfied, the HOD will enter the registration in the Register of Private Health Establishments. If the registration is refused, the applicant has a right of appeal to the MEC.[15] A private healthcare establishment must also be licenced. The licence that is issued is valid for one calendar year. An application for renewal of a licence must be submitted not less than 60 days before the expiry of the licence. Once an application for renewal has been submitted, the HOD must ensure that an inspection is done.

[26] Regulation 14 of the 2014 Regulations is very similar to the parameters laid down in section 36 (3) of the National Health Act[16], pertaining to the issuance

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[13] In terms of the 1980 regulations
[14] This is in terms of Regulation 15.
[15] This is in terms of Regulation 17.
[16] Section 36 of the National Health Act 61 of 2003 provides as follows:-

***"Certificate of need***

*36 (1) A person may not-*

*(a) establish, construct, modify or acquire a health establishment or health agency;*
*(b) increase the number of beds in, or acquire prescribed health technology at, a health establishment or health agency;*
*(c) provide prescribed health services; or*
*(d) continue to operate a health establishment or health agency after the expiration of 24 months from the date this Act took effect, without being in possession of a certificate of need.*

*(2) A person who wishes to obtain or renew a certificate of need must apply to the Director-General in the prescribed manner and muspt ay the prescribed application fee.*

*(3) Before the Director-General issues or renews a certificate of need, he or she must take into account-*

*(a) the need to ensure consistency of health services development in terms of national, provincial and municipal planning;*

of a certificate of need. Section 36 of the National Health Act has not yet come into operation, as the Proclamation which purported to bring this and several other sections of the National Health Act into operation was set aside by the

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*(b) the need to promote an equitable distribution and rationalisation of health services and health care resources, and the need to correct inequities based on racial, gender, economic and geographical factors;*
*(c) the need to promote an appropriate mix of public and private health services;*
*(d) the demographics and epidemiological characteristics of the population to be served;*
*(e) the potential advantages and disadvantages for existing public and private health services and for any affected communities;*
*(f) the need to protect or advance persons or categories of persons designated in terms of the Employment Equity Act, 1998 (Act No. 55 of 1998), within the emerging small, medium and micro-enterprise sector;*
*(g) the potential benefits of research and development with respect to the improvement of health service delivery;*
*(h) the need to ensure that ownership of facilities does not create perverse incentives for health service providers and health workers;*
*(i) if applicable, the quality of health services rendered by the applicant in the past;*
*(j) the probability of the financial sustainability of the health establishment or health agency;*
*(k) the need to ensure the availability and appropriate utilisation of human resources and health technology;*
*(I) whether the private health establishment is for profit or not; and*
*(mi if applicable, compliance with the requirements of a certificate of non-compliance.*

*(4) The Director-General may investigate any issue relating to an application for the issue or renewal of a certificate of need and may call for such further information as may be necessary in order to make a decision upon a particular application.*

*(5) The Director-General may issue or renew a certificate of need subject to-*
*(a) compliance by the holder with national operational norms and standards for*
*(b) any condition regarding health establishments and health agencies, as the case may be; and*
*(i) the nature, type or quantum of services to be provided by the health*
*(ii) human resources and diagnostic and therapeutic equipment and the establishment or health agency;*
*deployment of human resources or the use of such equipment;*
*(iii) public private partnerships;*
*(iv) types of training to be provided by the health establishment or health*
*(v) any criterion contemplated in subsection (3).*

*(6) The Director-General may withdraw a certificate of need -*
*(a) on the recommendation of the Office of Standards Compliance in terms of section 79(7)(6);*
*(b) if the continued operation of the health establishment or the health agency, as the case may be, or the activities of a health care provider or health worker working within the health establishment, constitute a serious risk to public health;*
*(c) if the health establishment or the health agency, as the case may be, or a health care provider or health worker working within the health establishment, is unable or unwilling to comply with minimum operational norms and standards necessary for the health and safety of users; or*
*(d) if the health establishment or the health agency, as the case may be, or a health care provider or health worker working within the health establishment, persistently violates the constitutional rights of users or obstructs the State in fulfilling its obligations to progressively realise the constitutional right of access to health services.*

*(7) If' the Director-General refuses an application for a certificate of need or withdraws a certificate of need the Director-General must within a reasonable time give the applicant or holder, as the case may be, written reasons for such refusal or withdrawal."*

Constitutional Court at the request of the State President in *President of the RSA and Others v South African Dental Association and Another,*[17]

[27] The scoring and qualification criteria are set out in Annexure "C" to the regulations. Annexure "C" is a scoring sheet that sets out various criteria and the applicable norms. Applications are scored out of 100 with applicants requiring a score of 80 or above.

[28] In terms of Regulation 35(1)(a) existing private health establishments which were registered before the commencement of the regulations remain registered under the 2014 Regulations.[18] However in terms of Regulation 35(1)(b), any alteration to a registered establishment or services rendered requires a new application process.[19] Regulation 35(2) makes provision for existing private hospitals and their compliance with the building requirements in annexure "B".

*Analysis of the parties' submissions*

[29] In its Heads of Argument, HASA criticizes various provisions. It also argues that the licencing procedures and requirements are cast in vague and contradictory terms, providing insufficient guidance to decision-makers and leading to uncertainty for the private healthcare sector.

[30] The MEC criticises HASA's application for being abstract. He argues that HASA's Heads of Argument seek to introduce new review grounds that were not properly anticipated in its founding papers. He also avers that HASA is in its Heads of Argument is raising new factual issues that the MEC ought to

[17] 2015 (4) BCLR 388 (CC).

[18] *"(1)(a) Subject to the provisions of paragraph (b), a health establishment which, at the commencement of these Regulations, was validly registered in terms of any applicable legislation, is deemed as being registered in terms of these Regulations."*

[19] *"(b) Any alteration to a private health establishment referred to in paragraph (a) or the services rendered therein must be applied for in terms of these Regulations, the provisions of which apply to such alteration."*

have been afforded an opportunity to address under oath. He furthermore criticizes HASA for having failed to make critical averments, in its founding affidavit, pertaining to its criticism of the various provisions of the 2014 Regulations.

[31] It is necessary to assess whether HASA's founding affidavit passes muster. The following remarks made in *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Tourism and Others*[20] are instructive. "It is desirable for litigants who seek to review administrative action to identify clearly both the facts upon which they base their cause of action and the legal basis of their cause of action." Although I am mindful of the undesirability of a judgment that is overburdened by extracts from the pleadings, I deem it necessary to quote *verbatim* from the salient averments made in the Founding Affidavit as this will immediately put the fallacious nature of this argument to bed. HASA *inter alia* makes the following averments in its Founding Affidavit.

> *"52.2 As things presently stand, HASA and its members lack the certainty to which they are in law entitled as to how the criteria will be determined and applied, both in relation to the establishment of private hospitals and also in relation to the continued and ongoing licensing and registration of private hospitals. There can be no basis for requiring that HASA and its members learn of these criteria on a case by case basis, but instead should be told of them up front.*
>
> *52.3 Furthermore, Regulation 14(1) imposes criteria that at best cannot be applied in the same way to the public sector and the private health establishments and at worst cannot be applied to the private health sector at all."*
>
> *52.3.1 This Regulation does not give recognition to the fact that private entities build private health establishments at great expense and with a view to a medium to long-term position. Particularly in circumstances where those private entities are accountable to shareholders and other investors- including investors who make decisions on investments across competing opportunities, of which private hospitals are but one instance- in this*

[20] 2004 (4) SA 490 (CC) at para [27].

*instance there can be no direct comparison between private and public hospitals.*

*52.4 As the Final Regulations stand, they are broad and vague. It is simply not possible, with reference to the Final Regulations as they read, to determine for example what would be considered "affordable" or what would be considered "accessible" except on a casuistic basis. A case by case determination is not legally cognizable and would not provide any measure of certainty let alone that degree of certainty that would be required to facilitate the establishment of and investment in new private healthcare establishments. Regulation 14(1) is replete with examples of just such terminology, including "equitable distribution and rationalization", "correcting inequities", "an appropriate mix", "alternative sources of healthcare", and so on.*

*53. Annexure C is the proposed adjudication tool to review applications and is similarly irrational and premature to the extent that it references the Regulation 14 criteria.*

*55. It is currently not possible for a person who wishes to establish a private health establishment in the Free State to have clarity on the regulatory requirements and criteria under which their application would be considered.*

*…*

*64. The Final Regulations also have a number of unfair and illogical results which have a disproportionately onerous impact on private health establishments. The decision therefore violates the principles governing the exercise of public power and undermines the very objectives of the Hospitals Act and the Final Regulations. The Department failed to balance the needs of private health establishments and the public with the need to regulate and monitor private hospitals. In doing so, the Department failed to reach a reasonable equilibrium between the various interests."*

[32] It is clear from the above extract that contrary to the MEC's criticism, HASA has laid a fairly all-encompassing factual foundation relating to registration, licensing, the requirements pertaining to alterations and extensions and the generally onerous nature of Regulation 14. These averments warranted a full response from the MEC pertaining to the impugned provisions and the Annexures relating thereto. What the MEC considers to be new grounds of

review are issues that were foreshadowed in HASA'S factual averments. In *My Vote Counts NPC v Speaker of the National Assembly and Others*[21], the court stated as follows:- "It is in any event imperative that a litigant should make out its case in its Founding Affidavit, and certainly not belatedly in argument. The exception, of course, is that a point that has not been raised in the affidavits may only be argued or determined by a court if it is legal in nature, foreshadowed in the pleaded case and does not cause prejudice to the other party."

[33] In my view, HASA's arguments also fall squarely within the ambit of the averments made by HASA and quoted in the preceding paragraphs, as well as other averments appearing elsewhere in the Founding Affidavit. The MEC had a choice in the manner in which he opted to respond to HASA's averments. He chose not to elaborate. He must accept that this choice was made at his own peril and not because the averments were not pleaded.

[34] Although HASA in its Founding Affidavit averred that the effect of the 2014 Regulations is to impose public obligations on private hospitals, it seemed to change tack in its Replying Affidavit when it stated that "HASA has never disputed that private hospitals may be subjected to public duties. HASA contests the manner and extent to which the final regulations purport to confer public obligations on private health establishment. That said, these aspects fall to be dealt with at the level of legal argument at the hearing of the application." In its Heads of Argument HASA conceded that private hospitals may be subjected to public duties. This concession was repeated by HASA's counsel during the hearing the application. International law supports the proposition that the state may impose obligations on public bodies in order to give effect to the right to access to healthcare.

[35] In General Comment 14 of the Committee on Economic, Social and Cultural Rights[22] it is stated that:

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[21] 2016 (1) SA 132 (CC) par [177].
[22] www.refworld.org/pdfid/4538838d0.pdf (28/11/2016).

> *'While only States are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society – individuals, including health professionals, families, local communities, civil society organizations, as well as the private business sector – to have responsibilities regarding the realization of the right to health. States parties should therefore provide an environment which facilitates the discharge of these responsibilities….*
>
> *'health facilities, goods and services must be affordable for all. Payment for health-care services as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households."*

[36] I agree with the postulation set out above. HASA's concession in that regard was thus correctly made. It is therefore unnecessary for this court to address itself to the many arguments made by the parties in relation to an issue which is no longer in dispute. This court therefore moves from the premise that private hospitals may indeed be subjected to public duties.

*Criticism in relation to Regulation 14(1)*

[37] The challenge to Regulation 14(1) has two prongs: first, that the assessment of 'need' imposes invalid public obligations on private hospitals, obliging private hospitals to compensate for the state's failures to provide access to healthcare. Second, the considerations are cast in impermissibly vague terms that will obstruct the development of private healthcare and therefore hinder access to healthcare.

[38] None of the provisions of Regulation 14 can be said to be unclear. Considered on its own, Regulation 14(1) does not seem to be onerous because there is no obligation placed on any entity to build a private health establishment or to make it available for public use. Furthermore, its provisions are not couched in peremptory terms, as it stipulates considerations

that “may” be taken into account. A wide discretion is thus given to a committee that has expertise and the wide discretion is exercised on the basis of factors stipulated in Regulation 14(1)(i)-(x). None of these factors must be applied rigidly. The provisions of Regulation 14(1) must be considered in conjunction with other sub-regulations. Regulation 14(3) provides that “qualification and scoring criteria are set out in Annexure “C”. This warrants consideration of Annexure “C”.

[39] Annexure C is a very integral document because it is the proposed adjudication tool to determine, in accordance with the provisions of Regulation 14, whether there is a need for the proposed health establishment. This Annexure lists the scoring and qualification criteria applicable to applications for establishment of a private health facility. It also reflects the norm against which the application will be considered and prescribes the number of points that must be allocated or deducted in various scenarios. It stipulates that an applicant must attain a minimum score of 80%, failing which it will be ineligible for registration and licensing. Annexure “C” is not a model of clarity.

[40] One example that sufficiently illustrates its fatal flaw is the considerations it prescribes as the norm in relation to the determination of the economic viability of an area. The word “area” is not defined. There are only two indicators stipulated, namely proximity to a university or an unemployment rate that is below 25%. Both indicators earn an applicant a total of 10 points. The form also states that this score is “critical”. An applicant who intends building hospital in an area where there is no university and where the unemployment rate is more than 25% immediately loses 10 points. This deduction is clearly irrational when considered in light of the obvious intended purpose of achieving a fair spread of hospitals in all areas. This applicant would therefore have to be scored out of 90 instead of a 100, immediately reducing its chances of achieving the 80% minimum score.

[41] The MEC's argument that Annexure C allows for an applicant to motivate where less points are allocated has no merit because the factors that the decision maker will take into account when deciding on the motivation for not complying with this "critical" requirement are unclear. Guidance is necessary here so that those considering the applications do not act arbitrarily. I am fortified in this view by the following remarks made by O'Regan, J in *Dawood and Another v Minister of Home Affairs and Others*[23]: "The scope of discretionary powers may vary. …Discretionary powers may also be broadly formulated *where the factors relevant to the exercise of the discretionary powers are indisputably clear*." (My emphasis). Since Regulation 14(1) must be considered in conjunction with Annexure "C", this regulation (Regulation 14(1)) as it currently stands does not, with reasonable certainty to all those who are bound by it, reflect what is required of the applicants of private health establishments and lends itself open to a case by case consideration of applications with no certainty of outcome. It leaves room for arbitrariness. It cannot be expected that certainty should be provided by way of disgruntled applicants approaching court on review. Litigation is costly and is often protracted due to the hierarchy of the courts.

*Criticism in relation to Regulation 2, 3 and 4*

[42] Regulation 2(1) provides that the 2014 Regulations apply to all private health establishments in the Free State. While Regulation 2(2) provides that the MEC may grant a private health establishment exemption from all or any of the provisions "if good grounds exist", there are no criteria set out for the exercise of that discretion. In my view, setting out criteria is necessary, given (i) the wide definition of health establishment and (ii) the provisions of Regulation 3 which require an application for registration even where an extension or alteration of a "private health establishment or services rendered in that establishment" is intended. These regulations could have far-reaching consequences for medical practitioners who intend running a small practice. (My emphasis).

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[23] 2000 (3) SA 936 (CC).

[43] HASA contends that there is no clarity on the procedure to be followed, the requirements that must be satisfied, or the identity of the decision maker in respect of licence renewals. It avers further that the distinction between registration and licensing is confusing and contradictory throughout the regulations. HASA contends that the fact that Regulation 4 mentions "registration of a licence" gives the impression that licensing comes before registration. That being the case, and given the provisions of Regulation 21(1) which stipulates that licensing should take place only once the private health establishment has been finally constructed, the risk to investors would be too high as they could expend a lot of resources on a building, only for the application for a licence to be denied. According to HASA, this would have a chilling effect on private hospitals.

[44] The texts of Regulation 3 and 4 speak for themselves. There is an obvious conflation between registration and licensing. I find it extremely astounding that the MEC persisted in arguing that that is not the case. Regulation 3(1) as it currently stands is ambiguous as it prohibits and criminalises the erection or variation or extension of a private health establishment before the application has been "approved and registered" and yet, by using the conjunctive "and", adds the requirement of licensing in terms of Regulation 21(3), which read with Regulation 21(1) requires dictates that licensing can only take place once the private health establishment has been finally constructed and is available for inspection.

[45] In trying to advance a lucid understanding of how the regulations pertaining to registration and licensing ought to be interpreted, the MEC in fact demonstrates that he, too, does not understand the full import of the applicable regulations. The MEC states as follows:-

> *"**After** a private health establishment **has been constructed**, an applicant will be required to apply for a **licence** in terms of regulation 21. At this stage, the only relevant enquiry is whether the private health establishment meets the specifications in annexure B to the final regulations."*[24] (My emphasis)

[46] However, the above is later contradicted by the MEC as follows:-

> *"Regulation 3 requires that persons may only **erect**, establish, maintain or control health establishments **if they have a licence to do so** and have been registered to do so."*[25]
>
> *....*
>
> *"To register a new health establishment, the application process set out in regulation 4, 5, 15, 16 and 17 (if necessary) must be followed. If successful, the application process culminates in the proposed health establishment being registered in a register of Private Health Establishments. **During this process, the licence application is also subjected to assessment under regulations 4, 5, 6, 14, 15, 16 and 17 but no final licence is issued at this stage**."*[26]
>
> (My emphasis).

[47] It is clear that on the MEC's own version, there is vagueness. The MEC's contention that the distinction between registration and licensing emerges with sufficient clarity from the regulations has no merit. The vagueness in the registration and licensing process does not end here. It is compounded by the provisions of Regulation 6[27], which refers to "application of a licence" without mentioning registration.

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[24] Para 69.3 of Answering Affidavit.
[25] Para 71.1 of Answering Affidavit.
[26] Para 71.2 of Answering Affidavit.
[27] Regulation 6, provides as follows:-
"*6. Publication and comments*
*(1) The applicant must within 30 days prior to submission of an* application for a license*, publish notification in a section of a daily newspaper circulating in the area where the service exists or is to be provided or the project exists or is to be located.*
*(2) The notice must inform members of the public where the application may be inspected and must specify that any interested party has 30 days from the date of publication of the notice to submit written comments to the Head of Department.*
*(3) The Head of Department must notify the applicant where comments have been received and provide the applicant with copies of the comments.*

[48] The MEC's argument that Regulation 14 has no application to registered private healthcare establishments because Regulation 14 applies only "at the outset" is devoid of any merit. It is clear from the provisions of Regulation 3(1) that Regulation 14 is triggered once an application for approval of an alteration or variation of health establishment or services is made. It therefore cannot be said that this regulation applies only at the outset.

[49] Furthermore, it was argued on behalf of the MEC that "nowhere in the affidavit does he address the process for or considerations relevant to applications to alter or extend a hospital's building or services". However, at para 45 of the Heads of Argument filed on behalf of the MEC, it is stated that "it is correct that Regulation 14(1) applies to the alteration and extension of buildings *and services*". The MEC's problems are compounded by the fact that the word "services" is not defined in the 2014 Regulations.

[50] In my view, the vagueness of the Regulations mentioned above is of such a nature that it cannot be said that applicants for private health establishments are in a position to know what is required of them so that they may act inaccordance with that knowledge. Considered against the backdrop of the judgment of the Constitutional Court in *Affordable Medicines Trust and Others v Minister of Health and Others*[28], Regulation 14 simply does not pass muster.

[51] I am of the view that the attack regarding the following regulations is unjustified. HASA quibbles about the expenditure that its members may have to incur for the annual renewal of the licence and argues that the period of validity of the licence ought to be longer. Notably, the predecessor to the 2014 Regulations, namely the 1980 Regulations, required the issuance of a

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*(4) No application may be accepted unless accompanied by proof that the publication has been made within the prior 30 day period."*

[28] supra

renewable certificate of registration by the HOD, which could be cancelled for failure to comply with certain conditions.[29] Significantly the issuance of the certificate of registration could be withheld if such registration was not in the public interest.[30] The proprietor also had to give particulars regarding the location of the hospital premises.

[52] The applicable regulations must not be read in isolation but in conjunction with the forms prescribed by the regulations. Form 4 includes the details that an applicant for renewal must submit to the HOD. Unlike the forms for applications for new acute and sub-acute private health establishments and for extensions to such licences there is no requirement for Form 4 to "provide detailed reasons in accordance with the criteria as set out in Regulation 14 as to why this application should be approved." It is clear that the application forms and the inspection process indicate what is required from a licence holder seeking renewal of their licence. I do not find the requirement for annual renewal of the licence to be onerous. Neither do I find any inadequacies in the renewal procedures in the regulations. It is also evident that there is no contradiction between Regulation 24(4) and Regulation 9(h). Regulation 9(h) is not intended to give the committee the power to renew licences. HASA's criticism of this regulation is therefore unfounded.

Remedy

[53] The vagueness of various provisions of the 2014 Regulations has already been brought to the fore in earlier paragraphs of this judgment. The question is whether the vagueness of the impugned regulations can somehow be salvaged by this court. The Constitutional Court has held that "where it is possible to separate the good from the bad in a statute and the good is not dependent on the bad, then that part of the statute which is good must be given effect to, provided that what remains carries out the main object of the

[29] Regulation 18 of Regulation 158 of 1980.
[30] This was in terms of Regulation 4(5) of the 1980 Regulations.

statute."[31] Courts should ideally seek to strike out or read down specific regulations rather than striking out an entire regulatory scheme.

[54] Having considered the impugned regulations, I am of the view that in as far as Regulation 2, 3, 4 and 6 are concerned, there are only a few patent errors and these are capable of correction by reading in or down. The phrase "*and a licence has been issued in terms of Regulation 21(3)"* could be excised from Regulation 3. Although a heading of a provision is not determinative of its meaning, the heading to Regulation 4 "*Application for registration of a licence*" somehow contributes to the vagueness. This ambiguity could be cured by deleting the words "of a licence" in the heading. The reference to the phrase "*and the concomitant licence"* in Regulation 4(1) also adds to the ambiguity. Similarly, Annexure "A" would have to be amended by excising the reference to a licence.

[55] It is evident that once changes are made to Regulations 3, 4 and the Annexures already alluded to earlier, Regulation 6 would also warrant attention. It seems to me that Regulation 6 is the only provision in the regulations that deals with publication of the application. When the whole registration and application process is considered, it would seem that Regulation 6 was intended to apply to an application for *registration*, not an application for a license. Why would members of the public have to comment only once the private health establishment has been finally constructed? What would the value of such comments be? The MEC's response pertaining to the criticism directed at Regulation 6 suggests that he does not realise this flaw, for in his defence of Regulation 6 as it currently stands, he states that the MEC may grant an applicant an opportunity of responding to the public comments by asking for additional information in respect of the "application"

[31] Johannesburg City Council v Chesterfield House (Pty) Ltd…Also see Minister of Health and Another v New Clicks South Africa (Pty) Ltd 2006 (2) SA 311 (CC) at para [16].

as contemplated in Regulation 5(1)[32]. Be that as it may, I am of the view that the vagueness in Regulation 6 can be remedied by replacing the words "application for a licence" with the phrase "application for registration".

[56] An insurmountable challenge for the MEC, in my view, is the content of Annexure "C", an important but flawed document that constitutes the tool for determining the scores to be allocated in respect of the criteria mentioned in Regulation 14. Clearly, this document needs much more than reading in or reading down or replacing words or phrases. This court must be mindful of the warning sounded in *Kalil NO and Others v Mangaung Metropolitan Municipality and Others*[33], where the court, with reference to the case of *Natal Joint Municipality Pension Fund v Endumeni*[34], stated as follows:

> *"…although it may of course at times be necessary to correct an apparent patent error in the language used in a statute or regulation in order to avoid an identified absurdity, courts should be slow to alter the words actually used and must guard against the 'temptation to substitute what they regard as reasonable, sensible or business-like for the words actually used', thereby legislating rather than interpreting."*

[57] Since Annexure C is the adjudication tool pertaining to the criteria set out in Regulation 14, the flaws identified in Annexure C impact on Regulation 14 as a whole. The upshot, then, is that it is currently not possible for prospective applicants who wish to establish private health establishments in the Free State to have clarity on the regulatory requirements and criteria under which their applications would be considered. I am of the view that any attempt at salvaging Regulation 14 by reading in or reading down will probably offend the doctrine of separation of powers. A remittal of the regulations to the MEC seems to be the only practical option here.

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[32] Regulation 5(1) provides that *"the Head of Department must within 7 working days of receipt of the receipt of an application contemplated by Regulation 4(1) consider the application to determine whether it has been properly completed or whether any additional information is required".*

[33] 2014 (5) SA 123 (SCA) at para 20.

[34] 2012 (4) SA 593 (SCA) at para [18]

*Costs*

[58] In the exercise of my discretion pertaining to costs, I have taken into account that each party is partially successful. The appropriate order under the circumstances is for each party to pay its own costs.

*Order*

1. Regulations 2, 3, 4, 6 and 14 of the 2014 Regulations and the Annexures relating thereto are set aside.
2. The order in 1 above is suspended for a period of six months to enable the MEC to effect amendments to the 2014 Regulations.
3. Each party to pay its own costs.

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**M. B. MOLEMELA, JP**

Musi, J and Daffue, J concurred with the judgment.

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| On behalf of applicant: | Adv. B. Leech SC<br>with C Steinberg<br>Instructed by:<br>Symington & De Kok<br>BLOEMFONTEIN |
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