**SUBMISSION ON THE HMI PROPOSED**

**REGULATORY INVENTIONS FOR LICENSING OF HEALTH FACILITIES**

**SUBMISSION DATE: 23 FEBRUARY 2018**

## 1. INTRODUCTION

Elsabe Klinck & Associates has had a number of healthcare professional societ clients who have run into challenges with the application of R158 of 1980,[1](commonly referred to simply as "R158") as it pertains to in-room procedures, or, as the R158 calls rooms where such procedures are done, "unattached operating theatres".

We thank the HMI for this opportunity to comment on the Discussion between Health Market Inquiry, National Department of Health, Provincial Departments and Relevant Stakeholders (as recording in the released "Discussion Paper"**)** on the Proposed Regulatory Interventions for Licencing of Health Facilities, 14 February 2018.

Due to the fairly limited scope of this matter, EKA and none of its clients wish to make any verbal submissions, but would appreciate consideration of this issue as the matter of R158 is being discussed.

## 2. COMMENTS ON OBSERVATIONS RELATING TO REGULATORY FAILURES IN HEALTH FACILITY LICENSING

### a. UNATTACHED OPERATING THEATRES AND THE IMPLICATION OF ITS INTERPRETATION

The licensing of private hospitals and "unattached operating theatre units" is currently regulated in terms of Government Notice 158, which was published pursuant to the provisions of the Health Act 63 of 1977. Many of the provisions of this Act have been repealed pursuant to the provisions of the National Health Act 61, 2003 **("NHA")**. Regulation 158, however, is still applied, despite the repeal of significant portions of the Health Act.

R158 makes no differentiation between "in-room procedures", and true "unattached operating theatres". Simply put, there is a misalignment between what is "legal" and what is "safe". For example, professional guidelines set out the safety of in-room sedation, as does guidelines on in-room injections and a-septic technique, etc. The SASA Adult Sedation Guidelines and Paediatric Sedation Guidelines are comprehensive in terms of the equipment, facilities and skills required for all types of sedation and collaborate with COSASA for the independent review of these facilities.

The legislation, not updated since 1980 (i.e. for 37 years!) has not kept pace with developments in medicine. Neither has it taken account of the constitutional dispensation, which requires access to healthcare to relate to both the availability, and the affordability of care.

An unattached operating theatre is defined in R158 as "an operating-theatre unit … not attached to a hospital or nursing home or maternity home, and where a patient operated on … may remain for a period not exceeding 12 hours." This definition far more aligns with the practical situation of day hospitals and smaller facilities were a particular type or types of operations are conducted.

Annexure A to the Regulations then describe the procedures that would have to be carried out in an unattached operating theatre, most of which, in practice, are not done in such a setting as (a) it is not clinically required and (b) it would unnecessarily add to the cost of rendering healthcare. Amongst the procedures listed are:

- Warts
- Circumcision (a very important public health policy objective)
- Stitching of wounds
- Injections into joints
- Examinations under anaesthetic

[1] Government Notice No R 158, Government Gazette No 6832. 1 February 1980 and amendments.

- Biopsies
- Various minor or small procedures under local anaesthetic
- Etc.

Many more are commonly, and safely undertaken in-room, many of which with technologies not previously available. Some of these require in-room sedation.

Establishing and running an "unattached operating theatre" requires a licence under regulation 7, which would, in practice means that every single practitioner who removes a mole in their rooms, does in-room injections, etc. would in effect require a licence. Apart from well-documented delays,[2] uncertainty as to the criteria to be fulfilled by this unique "form" of "unattached operating theatres", the sheer volume of work to grant such licences, would be staggering. The requirements of regulation 22 is also impossible to achieve.

Because of the existence of these regulations, malpractice insurance entities have warned that they would not cover any incident result from a procedure listed in Annexure A to R158.

In terms of the principles of constitutional law, under which access to healthcare must be made accessible, and also affordable, reasonable legislative and other measures such accompany the realisation of this goal. These regulations, as it stand to apply to in-room procedures, cannot be described as being reasonable, or rational, nor as achieving access to affordable care.

Significantly, effectively prohibiting the listed (and associated or similar types of-) in-room procedures, the power of hospitals are increased, as is the dependence of healthcare professionals on the licenced theatres of such facilities.

### a. GENERAL REMARKS ON HOSPITAL-LICENSING

The regulatory framework on the above, but also in general on hospital licensing should change, and there may be scope for a re-think in relation to the roles of healthcare professionals in hospitals (i.e. a review of the HPCSA rules and the applicable legislation in this regard). However, without addressing the matter of power (larger corporates or shareholder-driven entities versus individual practitioners, changes in the associated frameworks may leave healthcare professional independence and freedom to act in the best interest of their patients, dented. These concerns should, in an ideal environment, be possible to manage in the best interest of the patient. However, the regulatory oversight of the larger corporates answering to shareholders, remains unclear and under-resourced. Such additional power, without the concomitant checks and balances, would undoubtedly compromise the patient. Our clients already have many examples of this already taking place.

The role of the Certificate of Need (CON) remains contentious, and in the absence of draft regulations on this matter, is difficult to judge. Our clients support the intention of ensuring healthcare services are available where they are needed. Again the sheer magnitude of the CON, if applied to all practices and requiring regular renewals, may be too much to bear for the state. The criteria to be used are also extremely restrictive (and even outdated, the empowering provision dating from 2003) and, when read in the light of the previously submitted SASA research, might lead to highly mobile specialists leaving the country.

Licences must be managed to ensure that there is not an oversupply of beds in a particular area. However, the process is so complex that potential competitors and, especially more low-cost ones such as day-clinics, are constrained from competing against the existing monolithic entities. We strongly support any initiative that safely saves money and efforts that prevent people from having to be hospitalised or undergo procedures only when admitted into hospital. Healthcare procedures always carries a safety risk. Again, the lack of effective regulation (and enforcement!) and an effective, capacitated and empowered regulatory entity here makes it very difficult for the NDoH to both test and ensure that more cost-effectiveness and more competition leads to access to healthcare that is both affordable, of good quality and, ultimately, safe. The worst examples of how licensing processes can go wrong was recently on display during the Life Esidimeni hearings.

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[2] In, for example, *MEC for Health, Eastern Cape and Another v Kirkland Investments (Pty) Ltd* (77/13) [2014] ZACC 6 (25 March 2014).

## 3. REMUNERATIVE WORK OUTSIDE THE PUBLIC SERVICE

Paragraph 23 in the Discussion Paper pertains to this matter. Section 30(1) of the Public Service Act, 1994 (**"PSA")** prohibits "remunerative work outside the public service" ("RWOPS") unless "written consent" is obtained. It can therefore be argued that the purpose of Section 30 was to prevent fraud and corruption, avoiding the use of state assets for private transactions, dishonest dealings for self-enrichment, the wasting of state monies and "state time", the abuse of other state privileges like study leave, sick leave, etc.

We do agree that RWOPS should be managed and that abuse of this be avoided. The correct mechanisms to address this is through the employer-employee relationship (i.e. labour law). This reporting, however, must be free of any political or business vested interests. We see, however, more and more instances where the Board of Healthcare Funders refuse to issue PCNS numbers to some RWOPS-doctors, even if permission to do this was granted to them. Some medical schemes, in particular GEMS, have also instigated forensic inquiries, without cause, into practitioners with RWOPS permissions.

In a survey done by SASA, one of our clients and previously made available to the HMI, the results were that RWOPS relatively reduces the chance that a doctor would consider employment at private hospitals with "only" 50% of public sector specialist doctors doing RWOPS stating that they would consider employment by a private hospital. This is compared to the average of 63.8% of all (with and without RWOPS) public sector specialist doctors stating that they would consider private sector employment by a hospital group. RWOPS is, therefore, fulfilling its objective of attracting and retaining skills in the public sector.

## 4. ALLOCATION OF PRACTICE NUMBERS BY BHF

Paragraph 24 refers to the matter of the BHF issuing practice numbers and practice type numbers. The Council for Medical Schemes (CMS) may appoint a contractor to administer a Practice Code Numbering System (PCNS) on its behalf. The specific function being contracted out pursuant to sections 7 and 8 of the Medical Schemes Act, 1998 **("MSA")** and the duty to include a practice code on an account to a scheme is found in regulations 5 and 1 of the General Medical Schemes Regulations of 1999, as amended.

As every practitioner is registered at the HPCSA, with a specific number linked to a professional category. It appears that the PCNS is being used for purposes that are health policy- or health politics-related, such as to limit the supply of providers, to control numbers and business models, to exclude certain providers from practice numbers (e.g. device companies providing products and services associated with those products, etc.). None of those objectives are authorised by the MSA.

We support, therefore, the HMI proposal that any practice number system be incorporated into a licensing process, and, further, that this apply to practitioners who are, themselves, licensed to practice by their regulators (e.g. SANC and HPCSA).

## 5. CONCLUSION

We trust that the aforementioned information will be helpful, in particular in light of the HMI mandates on access to healthcare, increased competition (which is clearly enhanced through allowing in-room procedures that are proven to be safe and cost-effective), as well as addressing issues relating to practice numbers and RWOPS.

Should further information be required, we'd be more than willing to liaise with affected professional societies. Our lead staff at Elsabe Klinck & Associates (Pty) Ltd ("EKA") on this matter can be contacted as follows:

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