SASCI

South African Society of Cardiovascular Intervention

SASCI Submission

on the Draft Certificate of Need Regulations,

Notice No 528 of 15 June 2021

1. Introduction

South African Society of Cardiovascular Intervention (SASCI) is an organisation of physicians, scientists, and allied professionals with the purpose to advance the development of cardiology and coronary revascularisation and to provide minimally invasive, image-guided diagnosis and treatment of cardiac medical conditions.

It also acts in an advisory capacity to funders; industry; members and the government on matters relating to interventional cardiology. The latter is a branch of cardiology that deals specifically with catheter-based treatment of heart diseases and includes procedures such as angioplasty and Trans Aortic Valve Implantation (TAVI). The society is also a key enabler of CPD accredited education in interventional cardiology.

SASCI is affiliated as a Special Interest Group with the SA Heart Association and developed this submission with support from SA Heart.

Cardiovascular disease is the leading non-communicable cause of death in South Africa, and contributes significantly to morbidity.[1] Cardiovascular care in both the public and private sectors require access to specific technologies, equipment and facilities, such as catherization laboratories (cath labs). Practitioners also work in emergency rooms and intensive care units. The support of clinical technologists to operate key technologies, and specialised nursing professionals, are critical. Many of our patients also require admission into rehabilitation centres and/or at step-down facilities.

SASCI also understands that one of the key recommendations of the Health Market Inquiry was that the health facility licensing system, which are not optimally functioning, had to be replaced through the implementation of the Certificate of Need (CON) system. SASCI has also noted that the NHI system of

[1]See, for example: http://www.heartfoundation.co.za/wp-content/uploads/2017/10/CVD-Stats-Reference-Document-2016-FOR-MEDIA-1.pdf; https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30476-5/fulltext; http://www.uct.ac.za/sites/default/files/image_tool/images/292/Publications/Cardiovasc.pdf; etc.

accreditation for all service providers (practices, hospitals and the likes) will depend on the practice having a CON in place, as well as accreditation by the Office of Health Standards Compliance.

2. General comments

The Draft Regulations should draw its existence from the empowering provisions in the National Health Act, 2003 (NHA). The CON aims to give effect to the right of access to healthcare by ensuring an equitable distribution of healthcare establishments (e.g. to address the situation identified by the HMI, namely that hospital licences are not granted on need, and that where a hospital is set up, demand is created). This aspect is not addressed in the Draft Regulations at all.

Sections 36 to 39 of the NHA can be summarised as requiring regulations on -

- Applicable to establishment, construction, medication or acquisition and the continuation of health establishments or agencies;
- The prescribing of beds, technology and services, on particular the "nature, type or quantum" of services;
- Consistency in health planning;
- Equitable distribution of services;
- Mix of public- and private establishments and the effect on existing facilities;
- The patient population (demographics);
- Employment Equity in the SMME sector;
- Research & development;
- Ownership structures and perverse incentives;
- Quality of healthcare and compliance with national norms & standards;
- Financial sustainability;
- Human resources and training;
- Health technology; and
- For-profit / not-for-profit establishments and PPPs.

The Draft Regulations however leave most of these matters unattended, and the bulk of the regulations are a re-iteration of "GNR.158 of 1 February 1980: Regulations governing private hospitals and unattached operating theatre units" (R158) relating to mainly infrastructure and general equipment requirements. Draft regulations 10 to 34, i.e. the bulk of the "new" regulations are largely a verbatim reiteration of the current, outdated- and much criticized *hospital* licensing criteria.

It is significant that, whereas R158 applies to private hospitals, the CON empowering sections apply to all health establishments as defined in the NHA: all types of private practices, public health facilities, etc. the CON regulations also do not recognise the different categories of establishments[2] as published in regulations under the NHA in 2012 (GNR185 of 2 March 2012), which also prescribes the services, and would therefore impact the human resource, technology, training, research and other aspects of the CON set out in sections 36 to 39.

Simply-put, the R158-one-size will definitely not fit all. The Draft Regulations therefore does not align with the 2003 NHA and its associated systems and regulations, as opposed to the R158 which is based on the apartheid-era 1977-Health Act.

SASCI and SA Heart mandates that the cardiology profession be consulted prior to the finalisation of CON regulations relating to practices, facilities such as hospitals and the requirements set for technology, infrastructure and staffing requirements, as well as the financial viability of cardiology practices in outlaying and rural areas.

SASCI is also concerned about the following important aspects, not duly considered when these drafts were put up:

- The very same NHA governs quality of care (chapter 10 of that Act) and therefore aspects of quality of care and norms and standards do not require re-hashing (and possible contradictory provisions) in the CON draft regulations, it should simply refer to the Office of Health Standards Compliance system. GN 67 of 2 February 2018 on the "Norms and standards regulations applicable to different categories of

[2] District, regional, tertiary and central hospitals, including the numbers of beds and services rendered in each, as well as specialized hospitals (psychiatric, TB, infectious diseases and rehabilitation facilities). Private sector facilities are divided into "for profit" and "not for profit".

health establishments" already contains norms and standards that should be recognised, and not recreated in the CON system.

- No mention is made that these regulations repeal R158, or how it would supersede provincial licensing systems.
- The application of these regulations to all health establishments, public and private, and encompassing not only hospitals, but also private practices owned by professionals registered at the HPCSA (governing some 19 different professional groupings), Pharmacy Council, Nursing Council, Allied Health Professions Council, etc.
- Training is also governed, at least in part, by the NHA itself, the above professional councils and the SA Qualification Authority. The same applies to research activities, the principles of which are covered in the NHA, together with health products legislation. Reference to training appear in the CON application form, but appears to pertaining to nursing only.
- There is currently no Essential Equipment List / Medical Device List, which should be based on regulations to be made under section 90(1)(d), so the imposition of equipment standards through the Draft CON regulations could create contradictions.

The level of detail to which some of the provisions in the Draft Regulations go, i.e. they require a set of "screwdrivers" and "Allen keys", whereas regulations such as those relating to non-specific health establishments are far broader, is confusing – why this differences in approach, and why this level of minute detail – should / are these aspects necessary as part of the CON and its objectives, and if so, why are such details present in some, but not in other provisions?

Lastly, although the CON would also have to apply to health agencies, as defined in the NHA, namely:

"any person other than a health establishment—

(a) whose business involves the supply of health care personnel to users or health establishments;

(b) who employs health care personnel for the purpose of providing health services; or

(c) who procures health care personnel or health services for the benefit of a user,

and includes a temporary employment service as defined in the Basic Conditions of Employment Act, 1997 (Act No. 75 of 1997), involving health workers or health care providers."

There are no specific provisions in the Draft Regulations in this regard. Health agencies would include labour brokers operating in the health sector in, for example, nursing; agencies providing locum services; temp services; etc.

3. Specific comments

3.1. Definitions (regulation 1)

Many terms used in the Draft Regulations are not defined. For example, the regulations on "maternity units" previously as in R158 would only apply to private hospitals. But would that now, under the 2003-dispensation not also be defined as inclusive of regional hospitals, home-based delivery services and the likes?

One would also expect that both "health agency" and "health establishment" would be defined with reference to their definitions in the NHA.

3.2. Application (regulation 2) & Fees (regulation 4)

This regulation deals with the application form, but fails to set out any application process, or disputes and appeals processes. Section 39(2)(c) of the NHA requires not only the forms (it clearly being envisaged that there might be different forms) and procedures must be set out in detail.

This regulation mixes generalised substantive criteria (the premises, management, plans, etc.), with application formalities. A new criterion, not found in the NHA, is that the certificate must be "in the public interest" (regulation 2(2)(f)). This does not align with section 36(6) that refers to recommendations by the OHSC, access to healthcare, risk to public health, and compliance with norms and standards.

Of significance to SASCI is that all health establishments appear to have to be managed (it being unclear what it means to be "in charge" in draft regulation 2(2)(d)) by either a registered medical practitioner, or a dentist, in the case of dentistry services, or a nurse, in the case of nursing services. The HPCSA does not allow even between specialities, one practitioner to be in charge over another, and only persons in the same professional category may own, manage, and control a practice. The application of this rule to public

and private hospitals, is also not clear, in particular as private hospitals may not employ persons registered at the HPCSA.

Sub-regulation (3) requires building plans, lifts and ramps, writer proof of no objection by undefined and undisclosed "government departments concerned". This provision then also, but only in part, reiterates what is already in section 36.

It is impossible to comment on the fees listed in Annexure C, as no values are attached to it. There are four sets of application and inspection fees. It is unclear where the inspection powers is drawn from, as no such provisions exist in regulations 36 to 39.

3.3. Duration (regulation 3)

Regulation 3 and the application form in Annexure A states that the CON will be valid for a period of 20 years, but an existing facilities' CONs will only be valid for three years from date of issue (regulation 7(1)).

3.4. General CON requirements (regulation 5)

This draft regulation appear to apply to establishments not regulated elsewhere in the regulations, i.e. mobile units, private hospitals, operating theatres, maternity wards, etc. This would therefore cover all practices and what was previously termed "unattached operating theatres", i.e. facilities where procedures are performed but which are not situated in hospitals.

Apart from the criteria set under the application in draft regulation 2, the building criteria set in regulation 5(1)(a) to (o) are wholly or mostly inapplicable to cardiology practices, as health establishments. As stated above, criteria that relates to the empowering Act's sections 36 to 39 must be set in consultation with practitioners in (a) private practice located on hospital premises, (b) private practices located in other premises, (c) cardiologists working in public health facilities at various levels and (d) cardiologists working also in, but not being employed by, private hospitals.

3.5. Renewal of the CON (regulation 6)

The implication of this regulation, read with the duration of 20 years in regulation 3, and 3 years in regulation 7, is unclear – would existing health establishments have to renew every three years, and new establishments only every 20 years?

This renewal basically amounts to a new application, as the very same application form has to be used. It therefore is not a renewal, but a re-application at determined intervals. This is unduly onerous, and it would be impossible for the National Department of Health to undertake these re-assessments regularly for tens of thousands of sites.

3.6. Regulations 9 to 34

As stated above, these regulations draw on R158, which was developed under a different legislative regime, and only applies to private hospitals. There are no provisions making clear that R158 is being repealed, and what the status would be of provincially-specific licensing dispensations currently in place.

4 Conclusion

The Draft CON regulations do not give effect to the empowering provisions of the National Health Act. It unfortunately also does not attest to an understanding of the various types, categories and forms of healthcare establishments, nor of existing regulatory frameworks, some of which are included in the National health Act itself, and some outside of it, such as the Health Professions Act and Pharmacy Acy.

Given the fundamental flaws in the Draft Regulations, SASCI strongly recommends that it be withdrawn, that consultations with relevant stakeholders commence and that it only be republished after consideration of not only such input, but the findings of the Health Market Inquiry.

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