THE SOUTH AFRICAN MEDICAL ASSOCIATION SUBMISSION TO:

THE NATIONAL DEPARTMENT OF HEALTH

In respect of

Regulations relating to the certificate of need for health establishments and health agencies (Published 15 June 2021)

15 July 2021

Contents

1. INTRODUCTION

The South African Medical Association (SAMA) takes note of the gazetting of the *'Regulations Relating to The Certificate of Need for Health Establishments and Health Agencies'* on 15 June 2021, which initially came with a 4 week comment period up to 15 July but was subsequently extended to 15 August 2021 following complaints from stakeholders, including SAMA.

At the outset, SAMA expresses its dismay at the sudden publication of the Regulations relating to the contentious certificate of need (CON). Throughout the history of the CON legislation, SAMA has registered serious concerns with the CON legislation and its implications. Then and now, we note that the CON law could become detrimental to a country wishing to improve its population's access to health care facilities; if not carefully handled, the CON could see a reversal of the intended goal by causing unnecessary closure of doctors' practices, triggering exodus of doctors to other countries, and creating barriers to entry into the market by reducing competition, thus prompting a rise in healthcare costs to levels unaffordable to the majority. **Of critical concern is the fact that this legislation gives unfettered powers to the Health Minister over the health industry.** The potential damage goes beyond what is cited above and will be elaborated upon later in the document.

SAMA also expresses its disappointment with the four week timeframe initially allocated for submission of comments to the Government, although this has been extended by a month to 15 August 2021. The extremely short comment period illustrates insensitivity to stakeholders, including our organisation, which by its very nature as a membership-based organisation must ensure exhaustive consultation with its vast membership in its various categories. We totally condemn/reject such narrow comment periods. This sentiment is shared by many other health and medical bodies affected by this law. Notwithstanding the Health Department's earlier assurances that "nothing will be done without full consultation[1]", the Regulations were published clandestinely with an impossible comment period. That approach cannot be logically construed as "full consultation". As was done during NHI consultations, we urge the National Department of Health to allocate sufficient time to thoroughly 'work with' each

[1] https://health-e.org.za/2014/06/19/opinion-doctor-bodies-speak-certificate-need/

stakeholder (or stakeholder groups) on developing the CON regulations prior to publishing them.

SAMA further advises that, as always, our organisation is committed to working constructively with the Department of Health on health policy matters affecting our country. We are open to navigating mutually agreeable solutions on this controversial CON legislation. Nevertheless, in the event of failed negotiations with Government, we will be partnering with other affected stakeholders in the industry to find solutions and to take appropriate action to ensure that the impasse is resolved to the satisfaction of all concerned parties. SAMA tries at all costs to avoid the litigation road but at times legal arbitration becomes the only apparatus remaining. Reference is made to the 2015 Constitutional Court judgement setting aside the President's proclamation on the CON[2].

SAMA submits that is impossible to comment on the Regulations at hand without deferring to the original piece of legislation containing the CON provisions, the National Health Act 61 of 2003, which reflects the primary intentions of the CON and contains a more comprehensive criteria for awarding (or denying) a CON to an applying establishment. This submission will therefore interrogate relevant sections of the National Health Act 61 of 2003.

2. BACKGROUND

When the parent legislation for the certificate of need, the National Health Act 61 of 2003, was initially passed in 2003, SAMA immediately mounted a multi-pronged response in opposition of the clauses on CON (primarily Sections 36-40). Laudable as the CON appeared in theory, SAMA was apprehensive of the dire impact of the CON on individual medical practitioners, including compromising of occupational freedoms, and the unconstitutionality of the CON law. SAMA felt that the CON law was self-defeating and in fact could threaten the very goal it sought to achieve. In 2003-2004, SAMA deliberated the CON policy at the highest levels in its organisation and set up an internal task team. Submissions were made to the Health Department, a letter was written to the President, and a march to Parliament was successfully held. SAMA also

[2] https://health-e.org.za/2015/01/29/judgement-constitutional-court-sets-certificate-need-legislation-aside/

sought legal counsel and consulted with international and national experts on the CON. A comparative analysis of CON implementation in other countries was also undertaken— which demonstrated that, among other things, in some countries with CON laws, enforced regulatory measures, as opposed to voluntary regulation, could result in higher administrative and care costs, thus presenting a financial constraints the government.

In 2015, SAMA was delighted by the setting aside by the Constitutional court of the President's proclamation to bring certain sections of the National Health Act into force starting 1 April 2014.

Debate over CON is still raging across the world. A recent a systematic review and cost-effectiveness analysis based involving 90 publications, showed that, in the USA states implementing CON laws, the expected costs of CON exceed its benefits[3].

2.1 SAMA'S CONCERNS DURING THE EARLY HISTORY OF THE CERTIFICATE OF NEED (2003 ONWARDS)

When the National Health Act 61 of 2003 was passed, SAMA raised a number of substantive concerns on the certificate of need as provided for in relevant sections of the Act. In retrospect, it is clear that the only differentiating factor between SAMA's initial viewpoint in 2003 and SAMA's current stance is the formulation and publication of the Regulations on 15 June 2021; SAMA's concerns are germane to both time periods and remain our stance.

Back then, in the early 2000s, SAMA submitted that the CON was problematic in the following respects:

1. The criteria for the regulations were unclear and there were no assurances in respect of the regulations;
2. It violates the free market principles of supply and demand and is an attempt to apply inappropriate regulatory measures;
3. It restricts freedom of economic activity as entrenched in the SA Constitution, and creates future economic uncertainty;
4. Family life could be unjustly disrupted, particularly if there was more than one medical practitioner in a family;

[3] https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-020-05563-1

5. Medical practices would be de-valued if a CON is non-transferable to a purchaser;
6. A patient's right to be treated by a medical practitioner of his/her choice is compromised.

At the centre of these concerns are the constitutional rights of doctors that might be infringed upon in the process, some of which SAMA's Legal Counsel recognized as: -

- ***Human Dignity*** - Everyone has inherent dignity and the right to have their dignity respected and protected;
- ***Freedom of Movement and Residence*** - Everyone has the right to freedom of movement and every citizen has the right to enter, to remain in and to reside anywhere in the Republic;
- ***Freedom of Trade, Occupation and Profession***- Every citizen has the right to choose their trade, occupation or profession freely.
- ***Property*** - No one may be deprived of property except in terms of law of general application and no law may permit arbitrary deprivation of property.

The above SAMA' prediction in 2003 that "the criteria for the regulations were unclear and there were no assurances in respect of the regulations" has come true, 18 years down the line. The Regulations are confusing and do not speak to the initial intention of CON. It is incomprehensible how the Regulations have become confounded with Office of Health Standards and Compliance (OHSC) standards.

3. CONCERNS WITH THE PUBLISHED REGULATIONS, 2021

A unique confluence of issues make the CON apparatus an untenable approach to achieve the intended goals in South Africa. In this section we present our major concerns with the CON legislation.

The Regulations address two distinct domains:

I. Features and processes for certificate of need application and administration.
II. Stipulations for facilities and specifically hospitals and operating theatres, setting standards mainly for physical construction. These standards might also impact on day clinics and some group practice environments.

In subsequent sections, our comments are presented according to these two domains.

3.1 COMMENTS ON THE CERTIFICATE OF NEED STIPULATIONS AND PROCEDURES

3.1.1 The Regulations in question are positioned to mark the culmination of a long process of attempting to institute a maverick instrument to govern geographical rationing of health services. **Unfortunately, there is a universal agreement among SAMA members that the CON legislation as currently proposed must be totally discarded, as it is too intrusive into a number of doctors' rights, does not measure up to the standards of the Constitution, and has many other grave unintended consequences.** SAMA vehemently argued in the past that the parent legislation for the CON, the National Health Act 61 of 2003, was riddled with fundamental flaws; that the way the way the CON sections are written is problematic and these must be taken back to Parliament[4].

- **SAMA calls for the CON clauses to be completely removed from the National Health Act.**
- Short of completely removing the CON from the National Health Act, the Government can have medical professionals officially excluded, by the National Department of Health, from future requirements to apply for a CON; provided they are not applying for a hospital or day clinic licence.
- Replace CON with a Licence, as suggested by the Health Market Inquiry.

3.1.2 In considering the Health Minister's responsibilities towards the making of CON regulations, as provided for in Section 39(1) of the National Health Act 61 of 2003, it is necessary to refer to the specific terminology used, namely "may" (as distinguished from "must"). Section 39(1) states that the Minister "may" make Regulations relating to the CON. "May" is discretionary, as opposed to "must" which is imperative. Unless the term "may" is arbitrarily defined by the Government as synonymous with "must", this means – in this particular instance

[4] https://www.iol.co.za/news/south-africa/kwazulu-natal/doctors-certificate-of-need-plan-shelved-1728710

– that the Minister of Health is not necessarily **obliged** to make regulations on the CON. **Given the unrelenting arguments against the CON instrument, the CON legislation must be relegated to the dustbin of history, and better options be explored.**

3.1.3 SAMA takes the position that the CON law has not been extensively and satisfactorily debated, yet the Government seems to display dogged determination to push through the legislation in the face of serious disapproval by the health and medical industry. SAMA avows that the Government must have worked with stakeholders, including affected medical representative bodies such as SAMA, in drawing up the regulations prior to publishing them for public comment. From our reading of Section 90(4)(b) of the National Health Act 61 of 2003, which states that "*If the Minister alters the draft regulations, as a result of any comment, he or she need not publish those alterations before making the regulations",* the implication is that the current 8 week comment period (15 June to 15 August 2021) could become the ONLY chance stakeholders have to influence this important legislation before the Minister makes his/her final decision. In view of this, SAMA submits that Government must go back to the drawing board and engage thoroughly with stakeholders.

3.1.4 The CON apparatus is an attempt by Government to mask its failure to provide adequate health infrastructure and economic systems in remote and rural areas, and failure to implement effective retention policies to sufficiently incentivise skilled workers to work there, and private institutions to set up facilities in such areas. If there existed well-equipped hospitals in the rural areas with a safe environment, young doctors might have been interested in being employed in those settings.

3.1. 5 The CON legislation gives unfettered powers to the Health Minister over matters in the health industry. SAMA raised this point repeatedly in many different submissions, including submissions on National Health Insurance (NHI) and the Office of Health Standards Compliance (OHSC).

3.1.6 Non-transferability of a certificate of need:

Annex B of the Regulations states that "this certificate is not transferable and must be renewed annually". As alluded to earlier in section 2.1(5) of this

document, SAMA draws attention to the magnitude of the risk this restriction poses, namely the blockage created if one hopes to sell the medical practice at some point.

3.1.7 Criteria for rejection of an application for a CON is not clearly set out in the Regulations. Arbitrary rejections might lead to litigation.

3.1.8 There is uncertainty on accountability for applying for the certificate of need. Is it the medical practitioner (who will provide the services) who must apply for the certificate of need or is it the owner of the property (health establishment), for example in the case of rented rooms?

3.1.9 SAMA is not clear how the distinction between existing vs new health establishments was arrived at with regards to how long a CON will be valid for: 3 years for existing health establishments and 20 years for new establishments?. Also, the exact number of years for which an issued certificate of need is valid is vague. Section 3 provides that a CON is valid for 20 years; section 7 stipulates 3 years for existing health establishments and agencies; while Annex B of the Regulations states that "this certificate is not transferable and must be renewed annually".

3.1.8 The application and inspection fees intended to be contained in Annex C, as contemplated by Section 2(1)(c) of the Regulations are missing.

3.1.9 The Regulations, in Sections 2(2)(d) and 2(2)(e), require a doctor, dentist, or registered nurse to oversee a health establishment. We draw attention to the fact that private institutions may have non-medical managers or CEOs.

3.2 COMMENTS ON INFRASTRUCTURAL REQUIREMENTS AND STANDARDS

Inputs/comments on this section are required from members of the medical profession, who are on the ground and are intimately involved with the day to day realities of rendering health services.

4. POSSIBLE SOLUTIONS AND WAY FORWARD ON THE CERTIFICATE OF NEED

4.1 SAMA strongly submits that the CON is clearly not a feasible system or solution for South Africa. SAMA contends that the CON should be removed from the National Health Act and other solutions jointly explored.

4.2 SAMA demands that consultative meetings takes place between SAMA (and its partners) and the NDOH in order to discuss solutions, in view of the impact of the CON legislation on the medical profession and implications for service delivery. There must be continuous inter-facing between SAMA and the Department of Health in order to eradicate the concerns that the Minister has extensive powers on matters that impact on professions, institutions, and service delivery.

4.3 Alternatives and variations of the certificate of need program:

In place of the currently proposed heavily stringent regulatory form of CON, SAMA suggests that perhaps some alternative or 'adjusted model' of the certificate of need can be considered, based on deliberations with stakeholders as well as lessons from other countries. These options must be seriously pondered upon before progressing to final enactment of any CON legislation.

We present two possible models below:

INCENTIVE MODEL:

The government must shoulder the blame for failing to create favourable conditions to recruit and retain medical graduates in the under-serviced and rural areas of South Africa. In the 27 years since the democratic era, had the government heeded calls to develop adequate infrastructure in deprived and rural areas as well as to properly remunerate and incentivise medical doctors to work or set up practices in underserviced areas, this could have contributed to a more favourable geographic distribution of health services today. We propose that the Government should invest more on "carrot" solutions in place of the current "stick" approach.

LICENCE MODEL:

SAMA has expressed its views on the issuing of certificates of need to facilities in a submission to the Health Market Inquiry (HMI) as well as in the public domain. We do not believe it is the best mechanism to achieve improved distribution of health services, nor that it is likely to be implemented in such a way that it improves access to healthcare services.

We do believe that, instead of a certificate of need, a licencing regimen can be considered and be made more transparent. We also believe that making the statistics on the number of beds, operating theatres, intensive and high care units available across the country will be useful for capacity considerations.

4.4 The “sunset clause” could be upheld in order to provide certainty for existing medical practices, at the very least. This suggestion might, however, exponentially intensify the insecurity and demoralization felt by aspiring entrants into the private industry and might result in an exodus of doctors from South Africa.

4.5 New medical practices coming into an already saturated area could be controlled in a pre-determined manner according to criteria which are mutually agreeable to various stakeholders.

4.6 There needs to be some discussions and sensitivity regarding the issue of practitioners who were in the past barred from opening practices in some geographic areas in view of political motives.

4.7 As a pre-requisite for making well-informed CON related decisions, **Government,** and not health establishments, must generate – and make publicly available – accurate and credible demographic information and other information (needs assessment) required to make CON decisions. Data on disease profiles and patterns in all areas must be accurate and credible in order to be taken into account when deciding on whether or not to grant a CON. SAMA objects to the Regulations’ attempt (in section 2.3) to place this onerous responsibility on each individual applicant (health establishment) as part of the process for applying for a certificate of need.

4.8 If one of the aims of the CON is to curb over-servicing and perverse incentives for inappropriate practice, especially with regards to high technological equipment, then the perfect formula for equitable distribution would not be easily arrived at as other issues have to be investigated e.g. necessary infrastructure, backup support, infrastructural requirements, cost of equipment, etc.

4.9 Comment periods for any future consultations or calls for comments must be practicable and fair enough, to give stakeholders enough time to engage with the matter and be able to meaningfully influence the policy. **A minimum of 3 months is recommended**. The absence of honest consultation and transparency on the part of the Government will breed unnecessary tensions between the Government and industry stakeholders.

4.10 The effectiveness of CON programs continues to be a heavily debated globally. Therefore, the government must undertake a thorough investigation around the failures of the CON process in other countries so as to limit a repeat of the same problems is South Africa. In the USA for example, 12 states that had earlier implemented CON laws fully repealed their CON laws, while other states modified their CON legislation[5].

5. SAMA'S COMMITMENT TO WOKRKING WITH THE GOVERNMENT

SAMA is completely in support of improving access to health care in South Africa's underserviced areas, but does not believe the CON is the only instrument available to do so. Notwithstanding the ongoing strategic differences between SAMA and the Department of Health, there is a high level of commitment from SAMA to work with the Government and to influence CON policy in a constructive way.

[5] https://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx

6. CONCLUSION

Kind regards

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SAMA National Chairperson

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