

# **A BRIEF ON THE REGULATIONS RELATING TO THE CERTIFICATE OF NEED FOR HEALTH ESTABLISHMENTS AND HEALTH AGENCIES**

*Developed by SAMA, for SAMA*

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## **INTRODUCTION**

SAMA is presented with an opportunity to influence a critical element of health policy impacting heavily on the medical profession. These proposed Regulations need SAMA's serious attention. This brief seeks to provide a short summary of the issue at hand as well as previous SAMA engagement with the issue — in order to invite SAMA members' comments.

The above-named regulations on the certificate of need (CON) were published on 15 June 2021, with a **1 month comment period**. The deadline for submission to the Health Director General is **15 July 2021**.

According to the Regulations, the Regulations are being issued in terms of Sections 39(1) and 90(4) (a) of the National Health Act (NHA), 2003 (Act No. 61 of 2003).

Section 39(1) states that:

*The Minister may, after consultation with the National Health Council, make regulations relating to-*

- (a) The requirements for the issuing or renewal of a certificate of need;*
- (b) the requirements for a certificate of need for health establishments and health agencies existing at the time of commencement of this Act;*
- (c) the requirements for a certificate of need for health establishments and health agencies coming into being after the commencement of this Act; and*
- (d) Any other matter relating to the granting of a certificate of need and the inspection and administration of health establishments and health agencies.*

Section 90(4) states that:

- (a) The Minister must publish all regulations proposed to be made under this Act in the Gazette for comment at least three months before the date contemplated for their commencement.*
- (b) 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.*
- (c) The Minister may, if circumstances necessitate the immediate publication of a regulation, publish that regulation without the consultation contemplated in paragraph (a).*

The CON provisions apply to both public and private health facilities and practices, in line with the definition assigned to "health establishment" in the parent Act (the National Health Act 61 of 2003).

For NEW establishments, a certificate of need is valid for a maximum of 20 years (revocable), but if issued for an EXISTING health establishment or agency, it is valid for 3 years, which is particularly odd.

The Regulations address mainly facilities and specifically hospitals and operating theatres, setting standards mainly for physical construction but might also impact on day clinics and some group practice environments.

There are definitely some additional details which require additional attention from SAMA membership structures.

## **HISTORICAL BACKGROUND**

The Certificate of Need (CON) is entrenched in the National Health Act, 61 of 2003, which commenced on 2 May 2005. A number of sections of the Act did not come into effect at that time. One of these sections was section 36-40 which deals with the Certificate of Need.

Although these sections have remained dormant ever since the National Health Act 61 of 2003 was passed, they have been met with wide criticism by the medical fraternity. The SAMA Legal Department took a leading role when SAMA vehemently opposed the CON in the early 2000s. Back then, SAMA sought legal counsel, questioned the Constitutionality of section 36, made submissions to the Parliament, and offered to develop more realistic “shadow regulations”. In addition SAMA also examined / documented/ took important lessons from other countries globally regarding CON implementation.

At a SAMA National Council meeting during September 2003, the following resolution was adopted:

*"National Council, strongly opposing the CON for medical practitioners and/or practices, resolves that the CON and areas of concern in the National Health Bill be debated, and appropriate responses framed, as a matter of urgency by SAMA, under the direction of the Chairperson."*

In view of the above, a SAMA CON task team was established. During the first teleconference of the task team, the following was decided upon:

- It was time for SAMA to confront the DoH and fight the CON;
- A letter be written to the President of SA expressing objection and unhappiness with the CON and requesting him to intervene;
- The medical professionals should march to Parliament to express their dissent;
- Ammunition and arguments should be gathered by means of well-researched facts and senior legal Counsel' opinion on the matter should be engaged;
- SAMA would pursue legal action provided that they were convinced of the likelihood of winning such a case;
- Negotiations with COSATU should be initiated.

In 2014 the President made a proclamation to bring certain sections of the National Health Act, including the CON sections, into operation. This proclamation was

overturned by a Constitutional Court ruling in 2015, a move that was welcome by the medical fraternity including SAMA.

## **BRIEF ANALYSIS**

The Regulations emphasize that the CON is in the “public interest”.

The CON is implied in some recommendations of the Health Market Inquiry, including the establishment of a supply side regulator to set the rules of the game and scrutinize the private sector; and Replacement of Certificates of Need with hospital licenses for equitable spread of facilities across the country.

In accordance with Section 90(4) of the NHA, these Regulations commence 3 months from their date of publication (15 June 2021), and the Director General has no obligation to make further consultations after receiving public comments, before the Regulations commence.

The specific demands in the Regulations look very much similar (or aligned to) the OHSC norms and standards, thus effectively making the NHI-related norms and standards an ingenious concealment of a reincarnation of the CON.

Careful analysis is needed on whether the activation of some CON sections through these Regulations overrides the 2015 Constitutional ruling setting aside the CON.