South African Medical Technology Industry Association (*SAMED*)

SUBMISSION ON THE NURSING LICENSING REGULATIONS,

Regulations relating to the Conditions under which a Registered Person may Practice as a Private Practitioner, Notice No 3489, Government Gazette No 48969 of 2 June 2023

2 September 2023

To: paul.tsebe@health.gov.za / mihloti.mushwana@health.gov.za

1. Introduction

SAMED was founded in 1985 and is a not-for-gain voluntary trade association that represents the medical technology industry in South Africa. Its 152 members include manufacturers, distributors, and wholesalers, ranging from micro enterprises to large multinational companies who supply medical devices, medical equipment and invitro diagnostics (collectively termed medical technologies or medtech). SAMED is committed to ensuring a sustainable, transformed and ethical medical technology industry in South Africa. SAMED's members are governed by and required to adhere to the Medical Device Code of ethical marketing and business practice.

2. SAMED's interest in the Draft Regulations: the importance of nursing professionals in medical device implementation and management

Nursing professionals in private practice fulfil an extremely important role in supporting patients in both the private- and public sector.

The medical technology industry supply medical devices into the health sector and specifically to nursing professionals in private practice. The use and operation of these devices require healthcare professionals, nurses, patients, caregivers and/or family members to be trained on the appropriate use thereof, so as to ensure optimal usage and the best possible health outcomes. Incorrect medical device use, and incorrect readings of a device (where applicable) can have disastrous outcomes for patients. Nurses in private practice in turn, provide training to patients on how to use medical devices they need in terms of their treatment.

It is important that the healthcare practitioner who provides the necessary support to patients, caregivers and family members are trained with reference to the specific prescribed devices, their instructions for use, and with information relating to the reporting of adverse events.

Nursing practitioners are able to best fulfil the above, not only as being trained themselves on all aspects of a specific medical device, but also understanding the underlying condition of the patient and its implications for the implementation of the prescribed treatment. Such nursing professionals are also able to interpret the instructions of the prescribing healthcare professional, and, when appropriate, liaise with such a prescribing professional in relation to optimal care for a patient.

The medical technology industry relies on, supports and provides training to nurses in the following fields, who in turn provide the necessary assistance as set out above:

- Diabetic glucose devices and insulin pumps;
- Oxygen therapy, *continuous positive airway pressure*- and other breathing apparatus;
- Wound care, in particular advanced wound care devices;
- Home dialysis;
- Stoma care;
- Incontinence care;
- Home care, home monitoring;
- Etc

With the event of increasing "hospital at home" benefits by medical schemes,[1] one is bound to see a further increase in the need for private nurse practitioners, including those contracted to oversee the correct implementation of care that includes medical devices, such as monitoring devices.

3. Specific comments

Regulation 1 and regulation 2(2)(d): "additional qualification"

There are two concerns in this regard:

(a) The draft regulations are premised on all current private nurse practitioners being in possession of degrees, thereby being eligible for post-graduate qualifications. Where such were not in existence in the past, or not an option for a nursing practitioner, it means that s/he would never be able to be, or continue to be in private practice.

(b) For most of the activities undertaken by nurse practitioners in private practice pertaining to medical devices, there are no approved and registered qualifications. In SAMED's

[1] See, for example: https://www.discovery.co.za/medical-aid/hospital-at-home-for-members, https://www.bonitas.co.za/Hospital-at-Home and https://www.fedhealth.co.za/hospital-at-home-benefit/, amongst others.

understanding, the list of post-graduate qualifications presently recognised are: Child Nursing, Community Health Nursing, Critical Care Nursing (Adult), Critical Care Nursing (Child), Emergency Nursing, Forensic Nursing, Infection Prevention and Control Nursing, Mental Health, Nursing Midwifery, Nephrology Nursing, Occupational Health Nursing, Oncology and Palliative Nursing, Ophthalmic Nursing, Orthopaedic Nursing, Perioperative Nursing and Primary Care Nursing. However, there are no accredited qualifications relating to wound care, stomal therapy and diabetology.

The implementation of this criterion will therefore exclude large numbers of private nurse practitioners from continuing to offer the services they currently do.

Regulation 2: Licensing conditions

Regulation 2(2)(d) refers to the "specific discipline or field" in which the nurse practitioner intends to practice. This seems to indicate that a nursing professional working in the oxygen and breathing apparatus space would not be able to also conduct practice in, for example, diabetology or in wound care, etc.

A nursing practitioner in employment of a medical practice, or a diabetes clinic or managed care organisation, or a pharmacy, is currently able to provide services in these fields, without being in possession of said qualifications in the "specific discipline or field" and without being limited to only one field. The same applies for SAMED's members: contracting in private nurse practitioners would no longer be possible (as it would mean they might be working across fields), and the only possibility would be to employ such nurses. For example, a nurse practitioner in wound care, would not be permitted to work in diabetes. This means that it would not be possible to contract them as diabetic nurse educators, for example. This being in spite of the narrow association of diabetes and wound care.

The unintended consequence of this criterion therefore would be that it would be preferable for medical device companies to employ nurses rather than contract with independent nurse practitioners. This will lead to greater corporatisation of healthcare. It would also limit the freedom of choice of field(s) of exercising their profession, and the ability to advise patients independently (and in some cases even carrying competitor products), which contracted-in nursing professionals are able to do at present.

Regulations 1 and 5: Itinerant practice

The very nature of the services bulleted above is that services are provided where convenient and appropriate for the patient. Moving around, i.e. having an itinerant practice, is necessary. The sites could include the prescriber's practice, in a health facility and/or at the patient's home or even at their work. A practitioner may never undertake the specific service in his/her own practice, and may only provide those on an itinerant basis (e.g. oxygen and home dialysis implementation is only done at home, where the equipment would have been delivered).

Therefore, prohibiting itinerant practices go against the vary basic requirement of the specific services that private nurse practitioners render.

Regulation 3: Annual Reports

Reference is made to a "statistics form", but this has not been included for comment. Commenting on the reasonableness, or practicality, of the annual reports would necessitate disclosure of this form. This form is indicated as "Annexure B". It is unclear what "Annexure A" would be.

Regulation 4: Withdrawal

One of the circumstances (regulation 3(1)(d)) that would lead to the withdrawal of a licence, is where the person is also an employee at any other entity. This means that private nurse practitioners must either be employees, or in fulltime private practice.

In labour law it is possible to be an employee, and to have another business (e.g. a private practice), as long as this is in line with the employer's rules and subject to the employer's permission. If an employer is willing to accept that a full-time or part-time employee also conducts a private practice, SANC would have no authority in law to prohibit this. A nursing practitioner could be an employee in the mornings only, and run a private practice in the afternoon, or in the evenings.

Regulation 4(3) appears to relate to locums, and limits this to 3 months. It is possible that a practitioner may, for example, be ill for a longer period. It is recommended that the provisions in relation to locums and fixed-term employees be adopted, as is the case with the HPCSA and under the Labour Relations Act's sections 198 and 198A to 198D.

It is also unclear how regulation 4(3) relates to the locum provisions in regulation 6(3) as discussed below.

Regulation 6: Legal models

Regulation 6(1) appears to only permit two business forms of practice (apart from solus practice), namely partnerships and associations. It is unclear whether practicing in companies (probably Inc.'s) and/or trusts, for example, would be permissible. In SAMED's view this should be permissible, provided that the relevant rules of conduct are adhered to.

Although regulation 6(2) permits the sharing of rooms with a person registered at the HPCSA, the HPCSA does not allow such sharing of rooms – see HPCSA Ethical Rule 8A[2].

[2] GNR.717 of 4 August 2006: Ethical Rules of Conduct for Practitioners registered under the Health Professions Act, 1974 as amended.

Regulation 6(3) limits *locums* to other persons who also have a private practice. It is unlikely that private nurse practitioners would be able to stand in, in this manner for each other. Someone who does not have his/her own private nurse practice, but who otherwise is registered at SANC as being able to be in private practice, should be able to act as a *locum*. A *locum*, by its very nature, is someone who would be free to stand in for others, without themselves being bound to a practice.

Regulation 8: Fees

Kindly note that the BHF is, since the various Competition Commission and Tribunal rulings in the period around 2004, prohibited from publishing any fee list. Stipulating the fee levels with reference to medical schemes, amounts to fee setting, which would be anti-competitive, as well as not, in our understanding, within the powers of SANC.

Payment by medical device companies to private nurse practitioners for services at a fair rate and rendered in relation to medical device instructions and use, should be permissible, and should not be construed as commission. It should also be possible for nursing practitioners to sell health products, provided of course that the provisions of the Medicines and Related Substances Act, 1965 are adhered to, and that there are no kick-back or similar perverse arrangements relating to the supply of any product.

Regulation 10: Record-keeping

Records relating to children must be kept for at least three years after they reach the age of majority (i.e. after the age of 18). The HPCSA requires health records to be kept for at least 6 years after the last visit of a patient, unless specific legislation requires longer retention periods. Records relating to adverse health events concerning certain medical devices, have to be kept indefinitely. Please consult the medical device regulations in this regard.

SAMED proposes that record-keeping requirements align with the various legal frameworks in place for, for example, children, health & safety legislation, and where there are no criteria, that guidance such as that of the HPCSA, be followed.

Regulation 15: Transitional measures

It is submitted that it would be impossible for private nurse practitioners with established nursing practices, to obtain said licence, specifically if they have to wait for the accreditation of a post-graduate qualification, undertake such qualification or apply for recognition of prior learning, or access to a qualification without being graduated. It is literally impossible for a nurse currently not in possession of a degree (and there are a large number currently in private practice) AND do a post-grad diploma AND apply for a licence in 2 years' time. Expecting this also assumes there are accredited post-grad diplomas at SANC, which there are not.

SAMED believes that, not grandfathering existing private nurse practitioners from these regulations, would affect their rights to practice their profession, amount to the elimination of existing rights

and severely affect property rights. Nursing with established private practices will no longer have those practices, which form part of their property. The contracts they may have with medical device companies and others, would also be affected. Most significantly, it would also have a profound impact on the rights of access to healthcare of patients receiving services and appropriate instructions and training on the products they require to manage their healthcare.

4. Conclusion

SAMED appreciates the opportunity to comment. It can be contacted at the following email address and is available to clarify any aspect of this submission or provide further information.

Contact: tanya@samed.org.za; info@samed.org.za