Legal Limitations for Nurse Prescribers in Primary Health Care

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"The primary purpose of nursing is to provide the public with access to safe, competent basic health care and to do this, the nurse should be empowered to practice her/his profession within legal and ethical boundaries.

To ensure this, legislation should adopt a flexible approach to scope of practice issues."

SUMMARY

The nurse plays an important role in the delivery of primary health care services in South Africa. The primary purpose is to provide the public with access to safe competent basic health care and to achieve this, the nurse should be empowered to practice within legal and ethical boundaries. This paper explores and describes the limitations imposed by legislation on the nurse's ability to prescribe treatment in the primary health care field. The focus is mainly on the Nursing Act, the Pharmacy Act and the Medicines and Related Substances Control Act which highlights a number of limitations. It is concluded that empowerment of the nurse should not only include addressing the legal boundaries for practice, but also education and training opportunities to equip them with the expert knowledge and skills that they need to render a quality health care service.

OPSOMMING

Die verpleegkundige speel 'n belangrike rol in die lewering van primêre gesondheidsorgdienste in Suid Afrika. Die primêre doel is om aan die gemeenskap toegang te verleen tot 'n veilige, bedrewie basiese gesondheids-diens en om dit te kan doen moet die verpleegkundige in staat gestel word om binne 'n toelaatbare wetlike en etiese raamwerk te praktiseer. Hierdie artikel ondersoek en beskryf die beperkinge wat wagtegewing uitoefen op die verpleegkundige se vermoë om in die primêre gesondheidsorg arena behandeling te kan voorskyf. Die fokus is hoofsaaklik op die Wet op Verpleging, die Wet op Aptekers en die Wet op die Beheer van Medisyne en Verwante Stowwe wat 'n aantal van die beperkinge aandui. Daar word tot die slotsom gekom dat bemagtiging van die verpleegkundige nie net die aanspreek van die wetlike raamwerk behels nie, maar ook onderwys en opleiding wat die verpleegkundige moet toerus met die nodige vaardighede en kennis wat benodig word om 'n gesondheidsdiens van kwaliteit te lewer.

Introduction

The health care plan for South Africa and its shift of emphasis towards primary health care, has once again brought the important and extended role that nurses play in the delivery of the health services of this country to the fore. The purpose of this paper is to explore and describe the impact of legislation on the prescribing practice of the nurse in the primary health care field.
The nurse's scope of practice is broad and needs to be autonomous and accountable and legislation which embodies unrealistic restrictions should be re-examined and changes instituted. Nursing care is complementary to all other types of care, but makes its own unique contribution to health services as a whole" (WHO 1982:32).

Policy: Department of Health

The health care policy of the Department of Health focuses on primary health care and indicates that the nurse will be the client/patient's first contact with health care services. Primary Health Care is the cornerstone of health care for all (Department of Health 1996: 9).

Nurses in South Africa

Nurses in the Republic of South Africa are accountable and do make a unique contribution to health services, but are experiencing legal and other restrictions which seriously impact on their ability to make a contribution to the vision of "Health for all by the year 2000".

Legislation impacting on the prescribing practice of the registered nurse in primary health care

Nursing Act, No 50 of 1978 (South Africa 1978)

The nurse is the health professional who is available for twenty-four hours a day in most health care settings and is thus ideally suited to co-ordinate the actions of the multi professional health team, based on the health needs of patients. If the other members of the multi professional team are not available, she often needs to have the skills and discretionary ability to either do what needs to be done herself, or to refer. To co-ordinate patient care necessitates her moving into the grey areas of overlap of the practice of the nurse, medical practitioner and pharmacist (Bierman 1992:49).

This not only requires that the nurse should have the necessary skills, knowledge and expertise to do so, but she should also be legally and ethically enabled to do so.

Scope of Practice Regulations Government Notice 2598 of 30 November 1984 (South Africa 1978)

The nurse's scope of practice is broad and needs to be interpreted by each individual nurse according to her own specific knowledge, skills and expertise. To define a scope of practice can be hazardous because technological advances and the dynamic nature of nursing bring about changes in practice impossible to accommodate in a list of procedures or tasks. To express the scope of practice of nursing in lists and procedures negates the real nature of nursing and considers the technical aspects only (Bierman 1992:48).

The Scope of Practice Regulations contains some definitions which confine the practice of the nurse in primary health care and creates considerable confusion:

(a) "diagnosing" shall mean the identification of, and discriminating between physical, psychological and social signs and symptoms in man ....

The motivation for defining the word diagnosing in the scope of practice can be assumed to have been to avoid the making of what is termed and perceived to be a medical diagnosis, by the nurse (Bierman 1982:49). This definition is, however, confusing in that it creates the perception that there are different kinds of diagnoses and that nurses and medical practitioners are busy with different actions. Nurses in primary health care are certainly making "medical diagnoses" and the expectation is that they will also be making a "nursing diagnosis" to ensure comprehensive care for the patient.

(b) "nursing regimen" shall mean the regulation of those matters which, through nursing intervention have an influence on the preventive, promotive, curative or rehabilitative aspects of health care and includes the provision of nursing care plans, their implementation and evaluation thereof and recording of the course of the health problem, the health care received by a patient and its outcome whilst a patient is in the charge of the nurse ..... The term "nursing regimen" is often interpreted as the actual plan or blueprint of nursing care rather than the entire spectrum of events which starts with the first contact between the patient and the nurse and continues to the termination of that contact (Bierman 1992:50). It is further also often seen as a once off event when the patient is first assessed. Planning nursing and health care for a patient is a cyclical action where the patient is continuously assessed and the plan adjusted accordingly. The nursing regimen should dovetail with the regimens of the other members of the multi professional health team (Bierman, 1992:51). Even when planning nursing care only, the plan can never be adequate if the total treatment regimen of the patient is not taken into account. To ensure this, the nurse should have a sound knowledge of patho-physiological and pharmacological principles to ensure that the patient's needs are correctly interpreted and the regimen dovetails with that of the other team members. The nurse needs expert clinical knowledge at all times and not only when authorised in terms of Section 38A of the Nursing Act, 1978.

(c) "prescribing" shall mean giving the written directions regarding those treating, nursing care, co-ordinating, collaborating and patient advocacy functions essential to the effective execution and management of the nursing regimen ...

Prescribing of nursing care involves a thorough understanding of the treatment regimens of the other members of the multi professional team. The nurse needs to have a thorough understanding of all of the patho-physiological and pharmacological principles involved in the management of patient care to plan her own care. (Bierman 1992:51)

In the hospital situation a nurse would not prescribe medical care, but merely blends it into the nursing care. In the primary health care field the nurse is prescribing medical treatment and the above definition is therefore limiting her scope. The nurse should be legally equipped to perform the duties expected of her in order to meet the health needs of the community.

(d) "treatment" shall mean selection and performance of those therapeutic measures essential to the effective execution and management of the nursing regimen.

In primary health care settings a doctor is not always available
in the same way as in a hospital and the Government policy further states that the nurse will be the patient’s first contact with the health care system in primary health care. It is imperative that the nurse initiate medical treatment in a variety of diseases which are of local, regional or national importance, for example Tuberculosis, Sexually Transmitted Diseases, etc., which have a direct impact on morbidity and mortality rates in South Africa (Bierman 1992:52).

(e) Accountability of the nurse in primary health care
The nurse remains accountable for her actions and omissions in terms of Government Notice R387 of 15 February 1985 (South Africa 1978). Although the nurse is involved in the initiation of the medical treatment, she is still practising as a nurse and according to the regulations applicable to the nurse can, for example, be found negligent if it is found that she omitted to carry out nursing care.

Section 38 A of the Nursing Amendment Act, No 71 of 1981 (South Africa 1981)
During 1981 an amendment to the Nursing Act made provision for section 38 A. This provided for nurses in the employ of the state, local authorities or an organisation rendering a health service to perform certain acts in areas where the services of a medical practitioner or pharmacist are not available. This section does not provide nurses with the necessary empowerment to render an effective primary health care service. The following limitations exist:

1 This section does not make provision for midwives. The midwife in the service of the state must rely on a prescription by a medical practitioner for individual patients. This directly affects the effective functioning of midwives in clinics and day-hospitals (in the public and private sectors), where medical practitioners may not be available. Standing orders and protocols are made available for these nurses to administer, for example, Syntocinon and Vitamin K.

2 Authorisation is limited to nurses in the employ of state services, local authorities and certain organisations rendering a health service. It does not provide for the private nurse practitioner or the nurse in a private institution such as an occupational health clinic. There is some debate as to what the above-mentioned “certain organisations” include. Some say that it only refers to organisations in the public sector. Others are of the opinion that it could include organisations such as an occupational health service where the Director General could designate someone to authorise nurses.

3 The Director General of Health may delegate her responsibility to authorise nurses to prescribe to another practitioner in the employ of the state health department. Only the medical practitioner in charge of certain authorities delivering a health service, may authorise nurses and no provision is made for further delegation, making it impractical considering the distribution of primary health care services.

4 The nurses in the services of the Defence Force, the Mines and Correctional Services are therefore also excluded as they are not supervised by the Department of Health and are governed by other Acts. Although the Prisons Act states that there should be a medical practitioner in each prison to perform the functions stipulated in the Act, this function is almost always performed by the part-time, sessional district surgeon (this arrangement is provided for in section 6(2) of the Prisons Act). In practice it often happens that the nurse is on her own and has to provide a health service. (Bierman 1992: 38).

5 Provision is further made only for “physical” assessment and diagnosing - therefore excluding mental disorders.

6 Authorisation can only be granted in the absence of a doctor or pharmacist. This is in contradiction to the health policy of the Government.

7 Section 38 A states that only nurses authorised by this section may examine patients and promote family planning. This is not so and in fact, while supposedly empowering certain nurses, it inadvertently limits the practice of the majority of nurses.

Section 38 A will probably disappear in future. The handling and prescribing of medication are made provision for in the Medicines and Related Substances Control Amendment Act, where it actually belongs. It is believed that handling and prescribing of medication in all circumstances should be governed by one act.

Authorisation of nurses to prescribe
In addition to this, the authorisation of nurses was being done in a very uncoordinated and haphazard way. This should be done in consultation with the Nursing Council and the Pharmacy Council. Nobody knew who was authorised to prescribe or what criteria were used to authorise. The Department of Health, the SA Nursing Council and other role players developed some guidelines during 1997 to guide the persons responsible for authorisation which are the following (Ethics & Law 1998:46):

The nurse should:
(a) meet all the legal requirements of section 38A of the Nursing Act (No 50 of 1978, as amended), viz:
• be practising in a primary health care service in the service of the Department of Health, a local authority or an organisation performing a health service
• be registered as a nurse with the South African Nursing Council (SANC)

(b) have successfully completed a course approved by the SANC which will enable her to meet the following objectives:
Primary Health Care Nursing, Clinical Nursing Science, Health Assessment, Treatment and Care as well as knowledge and competency in:
Pharmacology
drug-drug relationships
drug-patient relationships
Disease profile in a geographical area
signs and symptoms related to the most prevalent conditions in the country
assessment skills
drug supply management
procurement, storage, supply, control and maintenance
Drug legislation
Prescribing
The ability to respond to the demands of the Essential Drugs Programme by giving support to and receiving support from other health professionals
Communication skills
Knowledge of the profession’s limitations
The nurse’s limitations.

The authorising officer shall:
(a) issue the authorisation to a specific person for a specific place;
(b) limit the authorisation to a period of two years from date of granting.

Currently authorisation to prescribe is granted by the Director-General of Health (usually her delegate at local level or the
Regulations Relating to the keeping, supply, administering or prescribing of medicines by registered nurses, Government Notice No 2418 of 2 November 1984 (South Africa 1978).

The restriction to schedule one to four medicines is contained in Regulation 2418 (promulgated in 1984). The exclusion of schedule 5, 6 and 7 drugs from the list of medication a nurse may keep or prescribe, is a big stumbling block for the psychiatric nurse and the nurse rendering care to the terminally ill. This restriction has, however, been removed in that the Medicines and Related Substances Control Amendment Act No 90 of 1997 which makes provision for the nurse to acquire, possess, use and supply identified schedule 1 to 6 drugs.

The Pharmacy Act, 1974 (South Africa 1974)

1 Section 29(3)(d) provides for nurses in the medical service of the armed forces to handle and supply medication to members of the armed forces under the supervision of the medical doctor or pharmacist provided that they are trained.

2 Section 29 (3)(e) allows any person registered or enrolled under the Nursing Act in a hospital or institution to keep medicine and supply it to patients, under the direction of a medical practitioner and in accordance with the Medicines Control Act. This allows for nurses to keep and administer medication in the hospital. No medication, not even unscheduled drugs, may be administered without the prescription of a medical doctor.

3 Section 29 (3)(f) refers to the keeping and acquiring of medicines by a person or organisation in order to deliver a service, but a nurse may only supply to the patient on the prescription of a medical practitioner. These last 2 sections limit the functioning of the nurse, because the medical practitioner, in many instances, is only available for a limited time. The reason why the organisation rendering a health service and the nurse in its employ is issued with a permit, is because a pharmacist or medical practitioner is not readily available.

4 The Pharmacy Amendment Act, No 88 of 1997(South Africa 1997) provides for:
   (a) inclusion in section 29 (3)(a) of the nurse as a practitioner who may keep or supply drugs to her patients in accordance with the Medicines Control Act.
   (b) provision for the Minister in section 29 (4) to, in consultation with the Pharmacy Council, grant a person not registered under the Pharmacy Act authorisation to perform a service specially pertaining to the scope of practice of a pharmacist on conditions determined by the Minister. This allows for nurses who may have to perform pharmaceutical duties.
   (c) the actions stated in section 29 (2) will in future be included in the regulations pertaining to the scope of practice. The following limitations for the nurse in the Pharmacy Act have therefore also been removed:
      (i)Section 29(2)(b)(i) limited her functioning in the primary health care field in that she needed a medical practitioner to prescribe medication for a patient;
      (ii)Section 29 (2)(d) with respect to “the furnishing of advice to any person with regard to any medicine supplied by him” which placed limitations on the practice of the Primary Health Care nurse, a large part of whose practice is based on health education including advice to patients on medication.

5 The Pharmacy Act only refers to the registered nurse - therefore excluding the midwife.

6 The Pharmacy Act does not make provision for the dispensing of a nurse’s script. An opinion from the State Law Advisor indicated that a pharmacist will probably have to dispense the script of a nurse in the employ of the State (Nursing Issues, 1997: 49).

The Medicines and Related Substances Control Act, No 101 of 1965 (South Africa 1965)

Currently the following is provided for:
Section 22 A (12) of this Act provides for issuing a permit to a nurse or organisation providing a health service:

(a) This permit is issued by the Department of Health after consultation with the Pharmacy Council.

(b) Such a permit enables the nurse/organisation to acquire, possess, use and supply specified substances. Each permit is accompanied with a list of substances that the permit holder may obtain. Applications to add items to this list may be made (and motivated) to the Department of Health.

(c) This permit does not authorise the nurse to prescribe any medication. No course done by the nurse will provide automatic authorisation to prescribe. For some time it was assumed that a permit holder is also allowed to prescribe. When this assumption was rectified, it created chaos especially in the private sector where private nurse practitioners had agreements/contracts with the local authorities to obtain vaccines and family planning medication in order to further extend the service into the community. By agreement these nurses provided statistical data of the utilisation of their services to the local authority. They further charged only for a consultation and not for the medication/vaccines administered or handed out. A legal opinion by the State Law Advisor indicated that, as the private practitioner is not employed by the local authority, she can not be authorised by the medical officer of health. In terms of the new Labour Relations Act, however, a contracted worker are also entitled to certain employment benefits and this opinion has been challenged (Nursing Issues 1997:49).

(d) Only schedule 1 - 4 substances may be obtained. Unscheduled substances may be kept. When a patient is on a schedule 5 or 6 treatment, the nurse may not handle, supervise, monitor or continue the patient’s treatment. The patient therefore has to be referred to the medical practitioner leading to a loss of man-hours and additional expenses for the patient. This negates the essence of, for instance, an occupational health service (Bierman 1992: 61). Most patients on psychiatric treatment receive schedule 5 medication. Nurses involved in caring for the terminally ill who needs pain relief is also restricted in terms of what they may use to make the patient comfortable.

(e) The Director General of Health will determine the conditions to which the permit will be subjected, e.g. a
permit is only issued to an occupational health service if a medical practitioner visits the service for at least one hour per week. In terms of these conditions it is the medical practitioner who is responsible for the control of medication, and not the organisation to whom the permit is issued. The running of the clinic and the responsibility for the medicines in the clinic in practice rests with the registered nurse and it is unrealistic to hold the medical practitioner responsible for patients and their treatment when he is there for only a short period.

The occupational health nurse providing a service to small companies, finds it increasingly difficult to provide a proper service. The registered nurse can usually not obtain a permit, thus not allowing her to carry the medicines with her to the various smaller occupational health services. The smaller industry cannot, and sometimes, does not want to obtain a permit to acquire, keep, use and supply medication.

(f) The permit is further only valid for the specific area or institution it was allocated to. Should the practitioner or the service relocate, the permit expires and new application should be made.

The Medicines and Related Substances Amendment Act, No 90 of 1997 (South Africa 1997) has not been implemented yet, but makes provision for:

(a) Section 22 A (14)(b)
Nurses may only prescribe medication after she/he has been authorised to do so by the S A Nursing Council. It must be stated clearly that authorisation will not automatically be granted on completion of any relevant or accredited course.

(b) Section 22 A (15)
The nurses may only acquire, possess, use or supply any specified schedule 1-6 substance if a license has been issued to the nurse or the institution which the nurse is working for. Such a license will be issued by the Director General of the Department of Health or his/her delegate in consultation with the Pharmacy Council and will be subject to the conditions as determined by the Director General. Licenses will only be issued to persons who have already been authorised. Each license will be accompanied by a list of medications that a particular person or institution may utilise and will only include substances from the essential drugs list (EDL). Nurses will therefore not be able to prescribe any scheduled 1-6 substance but only the listed schedule 1-6 EDL drugs. It appears that there may be more than one list that will be developed.

(c) Section 22 C(1)(a)
This section provides for a nurse to obtain a licence to compound and dispense medicines. In order to do this, the applicant must successfully complete a course approved by the Pharmacy Council as well as the payment of a prescribed fee.

Group practice

The health policy of the Government indicates that the private sector cannot offer primary health care services but that a full service (basic package) should be made available (Department of Health 1996:19). This means that a group practice needs to be established and that a nurse is to be included in the group practice. Nurses should be enabled to go into a group practice with other health professionals as an equal partner. The "Group Practice" concept has been under discussion for some time. A Therapeutic Alliance Discussion Group, convened by the Medical Association of South Africa, (now part of SA Medical Association) has been looking at various models. This discussion group consists of nurses, medical practitioners and pharmacists. Nurses seem to be the ones who are most progressive in their thinking (MASA 1997).

Currently the Acts and Regulations of the various professional groups prohibit group practice. Regulation 387 (Acts and Omissions) under the Nursing Act, 1978, (South Africa 1978) stipulates that the nurse may only go into a group practice with a person registered under the same Act. This limitation has been overcome by approval by the South African Nursing Council (SANC) of group practices/partnerships when a nurse applies to the SANC to go into partnership with another health practitioner.

A similar limitation in the rules (Ethical Rule 10) of the Medical, Dental and Supplementary Health Professions (now the Health Professions) Act (South Africa 1974) exists, legally making it impossible to form a multi professional group practice with persons not registered under the same act. Ethical rule 25 further prohibits the sharing of consulting or waiting rooms, or having an entrance through, or with the nameplate at the entrance of such premises with a person not registered in terms of the same Act.

Nurses may be employed and practice with practitioners registered in terms of the Nursing Act or other practitioners registered in terms of any Act in respect of a profession approved by the Nursing Council in a partnership and in association. At present the practitioners registered with the Health Professions Council may employ each other and may practice in partnerships, incorporated companies and associations. Pharmacists, on the other hand, may practice in any form of body corporate as well as partnerships. Practising in association usually means the sharing of premises and expenses, but each professional working for his own account. The ethical rules of the Medical, Dental and Supplementary Health Professions Act (South Africa 1974) also has an impact on the legal form a partnership can take. Ethical rule 8 prohibits the sharing of fees proportionally with any person or practitioner who has not taken a commensurate part in the services for which the fees are charged and ethical rule 9 prohibits the charging or receiving of fees not personally rendered.

Conclusion

The nursing profession is internationally well known for its historic flexibility to adapt and expand its role in response to changing and new health needs and the current situation presents yet another challenge in this regard.

There is a health care need out there that the nurses are willing to fulfill, including the private nurse practitioner. A lot of energy is currently going into devising creative ways to bypass legal limitations in order to meet those health needs. In some instances "eyes are closed" for serious transgressions of legislation where, for example, nurses are employed in the hospital pharmacy in rural areas - this constitutes exploitation of the nurse. On the other hand there are those who are spending a lot of energy in looking into/investigating what nurses do, constantly informing them of what it is they are doing wrong or where they are overstepping their legal boundaries. This energy could achieve so much more if it could be focussed on the end result, namely safe and efficient health care for all.

The primary purpose of nursing is to provide the public with access to safe, competent basic health care and to do this, the nurse should be empowered to practice her profession within legal and ethical boundaries. To ensure this, legislation should adopt a flexible approach to scope of practice issues.

The benefits in service delivery that can result from overlapping scopes of practice among different health professions, should be recognised as such as a dynamic approach to professional practice will enable greater public service.

It is imperative that the nurse practitioners receive the correct
training to empower them with the necessary skills, knowledge and expertise to fulfil the health needs of the country. The use of post basic nurse specialists with knowledge and skills in a particular area of practice beyond that of the generalist nurse, contributes maximally to providing the highest achievable quality of care.

REFERENCE LIST


Addendum

Dear Editor,

Re: South African Medicines and Medical Devices Regulatory Authority (SAMMDRA) Bill.

Further to my review article in this edition of *Curationis* on the legal limitations for nurse prescribers, I wish to bring to your attention that the SAMMDRA Bill currently under discussion makes provision for the following:

- the inclusion of registered nurses as practitioners who may handle and prescribe medication;
- the granting of authority to the South African Nursing Council to authorise the prescription of medicines by registered nurses;
- the necessity of obtaining a permit/licence to acquire, possess, use or supply medication to patients where the need exists;
- inclusion of medication ranging from schedule 2 to schedule 6 in the abovementioned provisions (limited to the Essential Drug List of the Department of Health); and
- the need to obtain an additional licence from the South African Pharmacy Council in order to compound and dispense drugs. This provision will be applicable to all health professionals except pharmacists.

Yours sincerely

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