

Ethical guidelines for good practice in the health care professions

Ethical guidelines for good practice in the health care professions

The following Booklets are separately available:

Booklet 1:	General ethical guidelines for health care professions	3
Booklet 2:	Ethical and professional rules of the Health Professions Council of South Africa as promulgated in government gazette R717/2006	20
Booklet 3:	National Patients' Rights Charter	79
Booklet 4:	Seeking patients' informed consent: The ethical considerations	86
Booklet 5:	Confidentiality: Protecting and providing information	103
Booklet 6:	Guidelines for the management of patients with HIV infection or AIDS	119
Booklet 7:	Guidelines withholding and withdrawing treatment	133
Booklet 8:	Guidelines on Reproductive Health management	146
Booklet 9:	Guidelines on Patient Records	162
Booklet 10:	Guidelines for the practice of Telemedicine	173
Booklet 11:	Guidelines on over servicing, perverse incentives and related matters	193
Booklet 12:	Guidelines for the management of health care waste	208
Booklet 13:	General ethical guidelines for health researchers	262
Booklet 14:	Ethical Guidelines for Biotechnology Research in South Africa	278
Booklet 15:	Research, development and the use of the chemical, biological and nuclear weapons	294
Booklet 16:	Ethical Guidelines on Social Media	307
Booklet 17:	Ethical Guidelines on Palliative Care	320



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

**GENERAL ETHICAL GUIDELINES FOR THE
HEALTH CARE PROFESSIONS**

BOOKLET 1

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcs@hpcs.co.za

Website: <http://www.hpcs.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, the practice of health care professions is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

Acknowledgements.....	iii
1. Introduction	1
2. Core ethical values and standards for good practice	2
3. How to resolve ethical dilemmas	3
4. What it means to have a duty	4
5. Duties to patients	5
6. Duties to colleagues and other health care practitioners	10
7. Duties to patients of other health care practitioners	10
8. Duties to themselves	11
9. Duties to society	11
10. Duties to the health care profession	12
11. Duties to the environment.....	12

ACKNOWLEDGEMENTS

The Health Professions Council of South Africa wishes to thank the following persons for their contributions towards the revision of the guidelines:

- The Committee for Human Rights, Ethics and Professional Practice of the Health Professions Council of South Africa for initiating and advising the review process.
- Ms RM Kekana (Chairperson), Prof A. Dhai, Prof D J. McQuoid-Mason, Ms V Amrit, Rev G Moerane, Dr C Vincent-Lambert, Mr R Mjethu and Dr TKS Letlape,
- Prof A. Dhai, Prof D.J. McQuoid-Mason, Dr N Msomi and LIFE*lab* for the development of the ethical guidelines for Biotechnology Research in South Africa.
- Prof D. J McQuoid-Mason for his editorial advice on the booklets
- Adv Mathibeli as the legal advisor, Ms N Manciya as Committee coordinator and Mr N Sipeka as the Council secretariat.

GENERAL ETHICAL GUIDELINES FOR THE HEALTH CARE PROFESSIONALS

1. INTRODUCTION

- 1.1 Being registered as a health care professional with the Health Professions Council of South Africa (HPCSA) confers on us the right and privilege to practise our professions. Correspondingly, practitioners have moral or ethical duties to others and society. These duties are generally in keeping with the principles of the South African Constitution (Act No. 108 of 1996) and the obligations imposed on health care practitioners by law.
- 1.2 This first booklet on general ethical guidelines contains value-oriented principles and express the most honourable ideals to which members of the health care profession should subscribe in terms of their conduct
- 1.3 More *specific ethical guidelines* and *rules* are derived from these general ethical guidelines. They offer more precise guidance and direction for action in concrete situations. They also make it possible for the HPCSA to implement sanctions against transgressors.
- 1.4 It is impossible, however, to develop a complete set of specific ethical prescriptions applicable to all conceivable real-life situations. In concrete cases, health care professionals may have to work out for themselves what course of action can best be defended ethically. This requires ethical reasoning.
- 1.5 This booklet lists thirteen core ethical values and standards that underlie professional and ethical practice in health care professions, and gives a short explanation of how one makes practical decisions through ethical reasoning. It then explains what a duty is, and catalogues the general ethical duties of health care professionals

[Note: In this booklet, the expressions “professional” or “practitioner” are used interchangeably to refer to health care practitioners].

[Note: Environmental Health Practitioners do not see patients]

2. CORE ETHICAL VALUES AND STANDARDS FOR GOOD PRACTICE

- 2.1 Everything ethically required of a professional to maintain good professional practice is grounded in core ethical values and standards – the latter are the directives that follow the core values. These core values and standards are presented as a linear list for the sake of simplicity.
- 2.2 In concrete cases, the demands of these core values and standards may clash, thus making competing demands on health care practitioners. The only way to address such clashes is through ethical reasoning.
- 2.3 The core ethical values and standards required of health care practitioners include the following:
- 2.3.1 **Respect for persons:** Health care practitioners should respect patients as persons, and acknowledge their intrinsic worth, dignity, and sense of value.
 - 2.3.2 **Best interests or well-being: Non-maleficence:** Health care practitioners should not harm or act against the best interests of patients, even when the interests of the latter conflict with their own self-interest.
 - 2.3.3 **Best interest or well-being: Beneficence:** Health care practitioners should act in the best interests of patients even when the interests of the latter conflict with their own personal self-interest.
 - 2.3.4 **Human rights:** Health care practitioners should recognise the human rights of all individuals.
 - 2.3.5 **Autonomy:** Health care practitioners should honour the right of patients to self-determination or to make their own informed choices, and to live their lives by their own beliefs, values and preferences.
 - 2.3.6 **Integrity:** Health care practitioners should incorporate these core ethical values and standards as the foundation for their character and practice as responsible health care professionals.
 - 2.3.7 **Truthfulness:** Health care practitioners should regard the truth and truthfulness as the basis of trust in their professional relationships with patients.
 - 2.3.8 **Confidentiality:** Health care practitioners should treat personal or private information as confidential in professional relationships with patients - unless overriding reasons confer a moral or legal right to disclosure.
 - 2.3.9 **Compassion:** Health care practitioners should be sensitive to, and empathise with, the individual and social needs of their patients and seek to create mechanisms for providing comfort and support where appropriate and possible.
 - 2.3.10 **Tolerance:** Health care practitioners should respect the rights of people to have different ethical beliefs as these may arise from deeply held personal, religious or cultural convictions.
 - 2.3.11 **Justice:** Health care practitioners should treat all individuals and groups in an impartial, fair and just manner.

- 2.3.12 **Professional competence and self-improvement:** Health care practitioners should continually endeavour to attain the highest level of knowledge and skills required within their area of practice.
- 2.3.13 **Community:** Health care practitioners should strive to contribute to the betterment of society in accordance with their professional abilities and standing in the community.

3. HOW TO RESOLVE ETHICAL DILEMMAS

- 3.1 The core values and standards referred to above are the foundation that grounds the general ethical guidelines in these booklets. Being general, such guidelines may be applied to many different concrete cases.
- 3.2 Questions arise as to how health care practitioners may use these guidelines to make practical decisions or choices about the provision of health care. For example, how does a guideline apply in a specific case? And, how do health care practitioners handle difficult situations where two (or more) principles appear to be in conflict?
- 3.3 Briefly, what is needed is *ethical reasoning*. In general, such ethical reasoning proceeds in four steps:
- 3.3.1 **Formulating the problem:** Determine whether the issue at hand is an ethical one once this has been done it must be decided whether there is a better way of understanding it.
- 3.3.2 **Gathering information:** All the relevant information must be collected - such as clinical, personal and social data. Consult authoritative sources such as these guidelines, practitioner associations, respected colleagues and see how practitioners generally deal with such matters.
- 3.3.3 **Considering options:** Consider alternative solutions in light of the principles and values they uphold.
- 3.3.4 **Making a moral assessment:** The ethical content of each option should be weighed by asking the following questions:
- 3.3.4.1 What are the likely *consequences* of each option?
- 3.3.4.2 What are the most important *values, duties, and rights*? Which weighs the heaviest?
- 3.3.4.3 What are the *weaknesses* of the health care practitioner's individual view concerning the correct option?
- 3.3.4.4 How would the health care practitioner himself or herself want to be treated under similar circumstances. –
- 3.3.4.5 How does the health care practitioner think that the patient would want to be treated in the particular circumstances?
- 3.3.5 Discuss your proposed solution with those whom it will affect
- 3.3.6 Act on your decision with sensitivity to others affected
- 3.3.7 Evaluate your decision and be prepared to act differently in the future

(Adopted from WMA – Medical Ethics Manual)

4. WHAT IT MEANS TO HAVE A DUTY
--

- 4.1 Ethical guidelines express duties. A duty is an obligation to do or refrain from doing something.
- 4.2 If we have a duty to another person, it means we are bound to that person in some respect and for some reason. We owe that person something, while he or she holds a corresponding right or claim against us.
- 4.3 An example of a right with a corresponding duty is the following: Suppose a health care practitioner reaches an agreement with a colleague that the latter will do a *locum* for him while he is away on family business: The colleague has a duty to do the *locum* and the health care practitioner has a right to the colleague's services. At the same time the colleague has a right to fair remuneration and the health care practitioner has a duty to compensate her/him.
- 4.4 To have a duty is to ask the question "What do I owe others?" To have a right is to ask the question "What do others owe me?"
- 4.5 Duties may be ethical, legal or both at once, and operate in the personal, social, professional or political spheres of our lives.
- 4.6 Healthcare practitioners fulfil different roles. Accordingly, they have different kinds of duties:
- 4.6.1 ***As human beings we have "natural duties"***, namely *unacquired general* duties simply because we are members of the human community - for example the natural duties to refrain from doing harm, to promote the good, or to be fair and just. As is the case with everyone, health care professionals owe these duties to all other people, whether patients or not, and quite independently of our professional qualifications.
- 4.6.2 ***As professionals we have "moral obligations"***, namely *general* duties we *acquire* by being qualified and licensed as professionals, that is, *professionals* entering into contractual relationships with patients - for example the professional duties to provide health care, relieve pain, gain informed consent, respect confidentiality, and be truthful.
- 4.6.3 ***Institutional duties***: Institutional duties are imposed upon health care practitioners working in specific institutions. They are specific to the health care practitioner's particular institutionalised role, for example the duties of a practitioner employed by a company, a health care practitioner working in a governmental research agency, or a doctor engaged in private practice. These duties are contained in employment contracts, job descriptions, conventional expectations etc. Institutional duties must be consistent with the ethical and legal duties of health care practitioners.
- 4.6.4 ***Legal duties***: Legal duties are duties imposed by the common law and by statute law (for example, the National Health Act (Act No. 61 of 2003) or the Health Professions Act, 1974) that require health care practitioners to follow certain procedures and to use particular skill and care when dealing with patients.

- 4.7 The duties listed in these general guidelines mostly fall into the second category – the general but acquired duties of a health care practitioner *as a professional*.
- 4.8 No duty is absolute or holds without exception irrespective of time, place or circumstance. This is not surprising, since different duties may prescribe quite opposite decisions and actions in a specific concrete or real-life situation. For example, our duties to our patients may compete with our duties to our employer. Or our duty to respect a patient's confidentiality may clash with our duty to protect innocent third parties from harm. (HIV/AIDS examples are particularly perplexing.) These are instances of conflicts of interest or dual loyalties.
- 4.9 No list of such duties is ever complete, but the catalogue of duties below presents a fairly comprehensive picture of what it is, in general, that binds any health care provider as a professional to his or her patients, as well as to others. However, it should be noted that these duties, if not honoured without justification, may constitute the basis for sanctions being imposed on professionals by the Health Professions Council of South Africa.
- 4.10 Any classification of duties is arbitrary, because specific duties may be owed to different parties simultaneously. Therefore, the classifications used below should be viewed only as a rough guide. However, underlying these duties is a set of core ethical values and standards of good practice that are regarded as *basic ethical principles*.
(see above para 2).

5. DUTIES TO PATIENTS

5.1 PATIENTS' BEST INTERESTS OR WELL-BEING

Health care practitioners should:

- 5.1.1 Always regard concern for the best interests or well-being of their patients as their primary professional duty.
- 5.1.2 Honour the trust of their patients.
- 5.1.3 Be mindful that they are in a position of power over their patients and avoid abusing their position.
- 5.1.4 Within the normal constraints of their practice, be accessible to patients when they are on duty, and make arrangements for access when they are not on duty.
- 5.1.5 Make sure that their personal beliefs do not prejudice their patients' health care. Beliefs that might prejudice care relate to patients' race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability.
- 5.1.6 If they feel that their beliefs might affect the treatment they provide, they must explain this to their patients, and inform them of their right to see another health care practitioner.

- 5.1.7 Not refuse or delay treatment because they believe that patients' actions have contributed to their condition, or because they – the health care practitioners - may be putting their own health at risk.
- 5.1.8 Apply their mind when making diagnoses and considering appropriate treatment.
- 5.1.9 Respond appropriately to protect patients from any risk or harm
- 5.1.10 Respond to criticism and complaints promptly and constructively.
- 5.1.11 Not employ any intern, health care provider in community service, or health care practitioner with restricted registration with the HPCSA, as a *locum tenens* - or otherwise - in their own or any associated health care practice.
- 5.1.12 Inform their patients if they are in the employ of, in association with, linked to, or have an interest in any organisation or facility that could be interpreted by an average person as potentially creating a conflict of interest or dual loyalty in respect of their patient care.
- 5.1.13 In emergency situations, provide health care within the limits of their practice and according their education and/ or training, experience and competency under proper conditions and in appropriate surroundings. If unable to do so, refer the patient to a colleague or an institution where the required care can be provided.

Adequately educated and/or trained

To qualify as adequately educated and/or trained:

- i. The individual practitioner must have successfully completed an educational training programme approved and accredited by the HPCSA within the field of practice and category of registration.
- ii. The individual practitioner must have successfully completed a training programme in a training entity/institution/hospital that has been accredited by the professional board, for training in that particular profession or discipline and for that particular competency.
- iii. The individual practitioner must, in order to be regarded as trained, have undergone an initial training period under the supervision, as defined in clause (i) above, of an entity accredited by the professional board for such purposes, and been credentialed in the successful completion of such training as defined.
- iv. The individual practitioner must have completed undergraduate or postgraduate training, the duration of which was laid down by the professional board.
- v. The individual practitioner must be evaluated and credentialed as having met the requirements of the training programme by an entity accredited by the Professional board (e.g. Colleges of Medicine, Universities, etc).
- vi. A short course will serve to enhance or maintain skills that have been credentialed and registered by the professional board.

- vii. The application of such training in care of the patient will be judged by the professional board by the standards and norms considered reasonable for the circumstances under which the intervention took place.

b. Sufficiently experienced

To be regarded as sufficiently experienced, a practitioner must:

- i. Have performed a minimum number of interventions annually to remain proficient, taking into account and judged by the standards and norms considered reasonable by the professional board, for the circumstances under which the intervention took place.
- ii. With regard to the introduction of new interventions within the practitioners' scope of professional practice, have undergone further appropriate training and credentialing as approved by the professional board."

c. Under proper conditions and appropriate surroundings

All interventions shall take place **under appropriate conditions and surroundings**. These are subject to judgment by the professional board as to what is considered reasonable in the circumstances and conditions, under which the intervention took place. No practitioner must embark upon an intervention unless it is in the patient's interest, and that it would be considered safe to do so, under the prevailing conditions and surroundings. The practitioner will be judged on what requirements would be reasonable to ensure that patient safety was protected.

5.2 RESPECT FOR PATIENTS

Health care practitioners should:

- 5.2.1 Respect the privacy, confidentiality and dignity of patients.
- 5.2.2 Treat patients politely and with consideration.
- 5.2.3 Listen to their patients and respect their opinions.
- 5.2.4 Avoid improper relationships with their patients and those who are accompanying the patient (for example, sexual relationships or exploitative financial arrangements).
- 5.2.5 Guard against human rights violations of patients, and not allow, participate in or condone any actions that lead to violations of the rights of patients.
- 5.2.6 inform the patient of the choice of having a chaperone in the room during an intimate examination
- 5.2.7 inform the patient if the practitioner will be having a chaperone in the room during an intimate examination

5.3	INFORMED CONSENT
-----	------------------

Health care practitioners should:

- 5.3.1 Give their patients the information they ask for or need about their condition, its treatment and prognosis.
- 5.3.2 Give information to their patients in the way they can best understand it. The information must be given in a language that the patient understands and in a manner that takes into account the patient's level of literacy, understanding, values and belief systems.
- 5.3.3 Refrain from withholding from their patients any information, investigation, treatment or procedure the health care practitioner knows would be in the patient's best interests.
- 5.3.4 Apply the principle of informed consent as an on-going process
- 5.3.5 Allow patients access to their medical records

For detailed information consult the HPCSA Ethical Booklet on Informed Consent

5.4	PATIENT CONFIDENTIALITY
-----	-------------------------

Health care practitioners should:

- 5.4.1 Recognise the right of patients to expect that health care practitioners will not disclose any personal and confidential information they acquire in the course of their professional duties, unless the disclosure thereof is:
 - made in accordance with patient's consent;
 - made in accordance with the court order to that effect;
 - required by law; or
 - In the interest of the patient. Section 14 and 15 of the NHA.
- 5.4.2 Not breach confidentiality without sound reason and without the knowledge of their patients
- 5.4.3 When claiming from medical schemes explain to patients the significance of ICD-10 coding and get the permission of patients to breach confidentiality when making a medical scheme claim.

For detailed information consult the HPCSA Ethical Booklet 5 on confidentiality: Protecting and Providing information

5.5	PATIENT PARTICIPATION IN THEIR OWN HEALTH CARE
-----	--

Health care practitioners should:

- 5.5.1 Respect the right of patients to be fully involved in decisions about their treatment and care even if they are not legally competent to give the necessary consent.
- 5.5.2 Respect the right of patients to refuse treatment or to take part in teaching or research.

- 5.5.3 Inform their patients that they have a right to seek a second opinion without prejudicing their future treatment.

For detailed information consult the HPCSA Ethical Booklet 3 on the National Patients' Rights Charter

5.6 IMPARTIALITY AND JUSTICE

Health care practitioners should be aware of the rights and laws concerning unfair discrimination in the management of patients or their families on the basis of race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition vulnerability.

For detailed information consult the HPCSA Ethical Booklet 3 on National Patients' Rights Charter

5.7 ACCESS TO CARE

Health care practitioners should:

- 5.7.1 Promote access to health care. If they are unable to provide a service, they should refer the patient to another health care practitioner or to a health care facility where the required service can be obtained, provided that in an emergency situation practitioners shall be obliged to provide care in order to stabilize the patient and then to arrange for an appropriate referral to another practitioner or facility. Section 5 of the NHA

For detailed information consult the HPCSA Ethical Booklet 3 on Patients' Rights Charter

5.8 POTENTIAL CONFLICTS OF INTEREST

Health care practitioners should:

- 5.8.1 Always seek to give priority to the investigation and treatment of patients solely on the basis of clinical need.
- 5.8.2 Avoid over-servicing: They should recommend or refer patients for necessary investigations and treatment only, and should prescribe only treatment, drugs or appliances that serve the needs of their patients. Rule 23A of the Ethical Rules of Conduct
- 5.8.3 Declare to their patients – verbally and by a displayed notice – any financial interest they may have in institutions, diagnostic equipment, or the like to which they make referrals, if the holding of such interest is permitted by the HPCSA. Rule 24 of the Ethical Rules of Conduct
- 5.8.4 Refrain from coercing patients or their family members to provide them (health practitioners) with gifts or any other undue benefit.

6. DUTIES TO COLLEAGUES AND OTHER HEALTH CARE PRACTITIONERS

6.1 REFERRALS TO COLLEAGUES AND POTENTIAL CONFLICTS OF INTEREST

Health care practitioners should:

- 6.1.1 Act in their patients' best interests when making referrals and providing or arranging treatment or care. They should not ask for, or accept, any undue inducement or incentive, from colleagues to whom they refer patients because it may affect or be seen to affect the health care practitioner's judgement.
- 6.1.2 Treat patients referred to them in the same manner in which they would treat their own patients.
- 6.1.3 Not service a patient in more than one capacity or charge fees based on more than one consultation where health practitioners are registered with more than one statutory council or professional board or in one or more categories within the same professional board.

Adhere to the guideline on self-referral and other referrals mentioned in Booklet 11 on Guideline on Over – Servicing, Perverse incentives and Related Matters (par 3.5).

6.2 WORKING WITH COLLEAGUES

Health care practitioners should:

- 6.2.1 Work with and respect other health-care professionals in pursuit of the best health care possible for all patients.
- 6.2.2 Not discriminate against colleagues, including health care practitioners applying for posts, because of their views of their race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability.
- 6.2.3 Refrain from speaking ill of colleagues or other health care practitioners. Rule 12 of the ethical Rules of conduct
- 6.2.4 Not make a patient doubt the knowledge or skills of colleagues by making comments about them that cannot be fully justified.
- 6.2.5 Support colleagues who uphold the core values and standards embodied in these guidelines.
- 6.2.6 Advise colleagues who are impaired to seek professional assistance.

7. DUTIES TO PATIENTS OF OTHER HEALTH CARE PRACTITIONERS

Health care practitioners should:

- 7.1 Act quickly to protect patients from risk due to any reason.

- 7.2 Report violations and seek redress in circumstances where they have a good or persuasive reason to believe that the rights of patients are being violated.
- 7.3 Report impaired colleagues who are a danger to the health of their patients in order that such colleagues may be provided with the necessary support to overcome their impairment and prevented from harming patients (See HPCSA Booklet 2 on Ethical and Professional Rules of the HPCSA Rule 25)

For detailed information consult the HPCSA Ethical Booklet 11 on Guideline on Over – Servicing, Perverse incentives and Related Matters.

8. DUTIES TO THEMSELVES

8.1 KNOWLEDGE AND SKILLS

Health care practitioners should:

Maintain and improve the standard of their performance by keeping their professional knowledge and skills up to date throughout their working life. In particular, they should regularly take part in educational activities that would enhance their provision of health services.

Acknowledge the limits of their professional knowledge and competence. They should not pretend to know everything.

Observe and keep up to date with the laws that affect professional health care practice in general and their practice in particular (for example, the provisions of the National Health Act (Act No. 61 of 2003)).

Update their skills and knowledge of ethics, human rights and health law as provided for in accredited Continuing Professional Development programmes.

For detailed information consult the HPCSA Ethical Booklet 16 on Continuing Professional Development.

8.2 MAINTAINING A PROFESSIONAL PRACTICE

Health care practitioners should:

- 8.2.1 Keep their equipment in good working order.
- 8.2.2 Maintain proper hygiene in their working environment.
- 8.2.3 Keep accurate and up-to-date patient records
- 8.2.4 Refrain from engaging in activities that may affect their health and lead to impairment.
- 8.2.5 Ensure that staff members employed by them are trained to respect patients' rights; in particular the right to confidentiality

9. DUTIES TO SOCIETY

9.1 ACCESS TO SCARCE RESOURCES

Health care practitioners should:

- 9.1.1 Deal responsibly with scarce health care resources.
- 9.1.2 Refrain from providing a service that is not needed.
- 9.1.3 Refrain from unnecessary wastage, and from participating in improper financial arrangements, especially those that escalate costs and disadvantage individuals or institutions unfairly.

9.2 HEALTH-CARE POLICY DEVELOPMENT

Health care practitioners should include ethical considerations, legal requirements and human rights in the development of health care policies.

Do they have a responsibility to develop policy?

10. DUTIES TO THE HEALTH CARE PROFESSION

10.1 REPORTING MISCONDUCT

Health care practitioners should:

- 10.1.1 Report violations and seek redress in circumstances where they have good or persuasive reason to believe that the rights of patients are being violated and / or where the conduct of the practitioner is unethical
- 10.1.2 Where it is in their power, protect people who report misconduct from victimisation or intimidation.

10.2 ACCESS TO APPROPRIATE HEALTH CARE

Health care practitioners should promote access to health care. If they are unable to provide a health service, they should refer the patient to another health care practitioner or health care facility that can provide the service.

11. DUTIES TO THE ENVIRONMENT

11.1 CONSERVATION OF NATURAL RESOURCES

Health care practitioners should recognise that they have a responsibility to ensure that in the conduct of their affairs they do not in any way contribute to environmental degradation.

11.2 DISPOSAL OF HEALTH CARE WASTE

Health care practitioners should protect the environment and the public by ensuring that health care waste is disposed off legally and in an environmentally friendly manner



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

**ETHICAL AND PROFESSIONAL RULES OF THE HEALTH
PROFESSIONS COUNCIL OF SOUTH AFRICA**

BOOKLET 2

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcs@hpcs.co.za

Website: <http://www.hpcs.co.za>

ETHICAL AND PROFESSIONAL RULES

Practice as a health care professional is based on a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society.

In the course of their professional work health care practitioners are required to subscribe to certain rules of conduct. To this end the Health Professional Council of South Africa has formulated a set of rules regarding professional conduct against which complaints of professional misconduct will be evaluated. These rules are reproduced in this booklet.

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

SCHEDULE	7
DEFINITIONS	7
INTERPRETATION AND APPLICATION	9
ADVERTISING AND CANVASSING OR TOUTING.....	9
INFORMATION ON PROFESSIONAL STATIONERY	10
NAMING OF A PRACTICE	10
ITINERANT PRACTICE	11
FEEES AND COMMISSION.....	11
PARTNERSHIP AND JURISTIC PERSONS.....	11
SHARING OF ROOMS	12
COVERING	12
SUPERSESSION.....	12
IMPEDING A PATIENT.....	13
PROFESSIONAL REPUTATION OF COLLEAGUES.....	13
PROFESSIONAL CONFIDENTIALITY	13
RETENTION OF HUMAN ORGANS	13
SIGNING OF OFFICIAL DOCUMENTS	14
CERTIFICATES AND REPORTS.....	14
ISSUING OF PRESCRIPTIONS.....	15
PROFESSIONAL APPOINTMENTS.....	15
SECRET REMEDIES	15
DEFEATING OR OBSTRUCTING THE COUNCIL OR BOARD IN THE PERFORMANCE OF ITS DUTIES.....	15
PERFORMANCE OF PROFESSIONAL ACTS.....	16
EXPLOITATION.....	16
MEDICINE AND MEDICAL DEVICES	16
FINANCIAL INTERESTS IN HOSPITALS	17
REFERRAL OF PATIENTS TO HOSPITALS	18
REPORTING OF IMPAIRMENT OR OF UNPROFESSIONAL, ILLEGAL OR UNETHICAL CONDUCT.....	18
RESEARCH, DEVELOPMENT AND USE OF CHEMICAL, BIOLOGICAL AND NUCLEAR CAPABILITIES	19

MULTIPLE REGISTRATION..... 19
MAIN RESPONSIBILITIES OF HEALTH PRACTITIONERS20
REPEAL.....20
ANNEXURES.....21

ETHICAL AND PROFESSIONAL RULES OF THE HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

NOTE

This Booklet contains the Draft Regulations concerning the ethical and professional rules that the Health Professions Council of South Africa (HPCSA) has recommended to the Minister of Health.

Health care practitioners who decide not to follow the guidance in this Booklet (including the Annexure), must be prepared to explain and justify their actions and decisions to patients and their families, their colleagues and, if necessary, to the courts and the HPCSA.

GOVERNMENT NOTICE
DEPARTMENT OF HEALTH

No. R. 717

4 August 2006

as amended by Government Notice No. R 68 of 2 February 2009.

HEALTH PROFESSIONS ACT, 1974 (ACT NO. 56 OF 1974)

**ETHICAL RULES OF CONDUCT FOR PRACTITIONERS REGISTERED UNDER THE
HEALTH PROFESSIONS ACT, 1974**

The Health Professions Council of South Africa, in consultation with the professional boards, has, under section 49 of the Health Professions Act, 1974 (Act No. 56 of 1974), made the rules in the Schedule.

SCHEDULE

Definitions

1. In these rules, any word or expression to which a meaning has been assigned in the Act shall bear such meaning and, unless the context indicates otherwise -

“Act” means the Health Professions Act, 1974 (Act No. 56 of 1974);

“annexure” means an annexure to these rules;

“association” means a form of where two or more practitioners practise for their own account, but share communal assets or facilities;

“board” means a professional board established in terms of section 15 of the Act;

“canvassing” means conduct which draws attention, either verbally or by means of printed or electronic media, to one’s personal qualities, superior knowledge, quality of service, professional guarantees or best practice;

“close collaboration” means consultation by a practitioner at one stage or another in the treatment of a patient with another practitioner and the furnishing by the latter practitioner, at the end of such treatment, of a report on the treatment to the practitioner whom he or she consulted;

“dental specialist” means a dentist who has been registered as a specialist in a speciality or subspeciality in dentistry in terms of the Regulations relating to the Specialities and Subspecialities in Medicine and Dentistry, published under Government Notice No. R. 590 of 29 June 2001;

“dispensing optician” means a person registered as such in terms of the Act and the Rules for the registration of Dispensing Opticians, published under Government Notice No. R. 2339 of 3 December 1976;

“impairment” means a mental or physical condition which affects the competence, attitude, judgement or performance of professional acts by a registered practitioner;

“independent practice” means a practice where a registered health profession is conducted by a health practitioner without the supervision of another health practitioner;

“itinerant practice” means a practice which a practitioner conducts on a regular basis at a location other than at his or her resident practice address;

“medical device” means a medical device as defined in section 1 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);

“medical scientist” means a person registered under the Act as a biomedical engineer, clinical biochemist, genetic counsellor, medical biological scientist or medical physicist;

“medical specialist” means a medical practitioner who has been registered as a specialist in a speciality or subspeciality in medicine in terms of the Regulations relating to the Specialities and Subspecialities in Medicine and Dentistry, published under Government Notice No. R. 590 of 29 June 2001;

“optometrist” means a person registered as such under the Act;

“pharmaceutical concern” means a company registered as such under the Pharmacy Act, 1974 (Act No. 53 of 1974);

“practitioner” means a person registered as such under the Act and, in the application of rules 5, 6 and 9 of these rules, also a juristic person exempted from registration in terms of section 54A of the Act;

“private practice” means the practice of a health practitioner who practises for his or her own account, either in *solus* practice, or as a partner in a partnership, or as an associate in an association with other practitioners, or as a director of a company established in terms of section 54A of the Act;

“public company” means a company registered as such under the Companies Act, 1973 (Act No. 61 of 1973);

“public service” means a service rendered by the state at the national, provincial or local level of government and includes organizations which function under its auspices or are largely subsidized by the state or recognized by a board for the purposes of these rules;

“resident practice” means a place where a registered health practitioner conducts his or her practice on a daily basis;

“rooms” means a physical structure, with an exclusive entrance and walled all round for the privacy of patients, the preservation of their confidentiality and the safe keeping of records, where a practitioner conducts his or her practice;

“section” means a section of the Act;

“specialist” means a practitioner who is registered as a specialist in a speciality or subspeciality (if any) in terms of the Regulations relating to the Specialities and Subspecialities in Medicine and Dentistry, published under Government Notice No. R. 590 of 29 June 2001, and who confines his or her practice to such speciality or subspeciality;

“supervision” means the acceptance of liability by a supervising practitioner for the acts of another practitioner; and

“touting” means conduct which draws attention, either verbally or by means of printed or electronic media, to one's offers, guarantees or material benefits that do not fall in the categories of professional services or items, but are linked to the rendering of a professional service or designed to entice the public to the professional practice.

Interpretation and application

2. (1) Failure by a practitioner to comply with any conduct determined in these rules or an annexure to these rules shall constitute an act or omission in respect of which the board concerned may take disciplinary steps in terms of Chapter IV of the Act.
- (2) Conduct determined in these rules or an annexure to these rules shall not be deemed to constitute a complete list of conduct and the board concerned may therefore inquire into and deal with any complaint of unprofessional conduct which may be brought before such board.
- (3) At an inquiry referred to in subrule (2) the board concerned shall be guided by these rules, annexures to these rules, ethical rulings or guidelines and policy statements which the board concerned or council makes from time to time.

Advertising and canvassing or touting

3. (1) A practitioner shall be allowed to advertise his or her services or permit, sanction or acquiesce to such advertisement: Provided that the advertisement is not unprofessional, untruthful, deceptive or misleading or causes consumers unwarranted anxiety that they may be suffering from any health condition.
- (2) A practitioner shall not canvass or tout or allow canvassing or touting to be done for patients on his or her behalf.

Information on professional stationery

4. (1) A practitioner shall print or have printed on letterheads, account forms and electronic stationery information pertaining only to such practitioner's –
 - (a) name;
 - (b) profession;
 - (c) registered category;
 - (d) speciality or subspeciality or field of professional practice (if any);
 - (e) registered qualifications or other academic qualifications or honorary degrees in abbreviated form;
 - (f) registration number;
 - (g) addresses (including email address);
 - (h) telephone and fax numbers;
 - (i) practice or consultation hours;
 - (j) practice code number; and
 - (k) dispensing licence number (if any).

- (2) A group of practitioners practising as a juristic person which is exempted from registration in terms of section 54A of the Act or a group of practitioners practising in partnership, shall print or have printed on letterheads, account forms and electronic stationery information pertaining only to such juristic person or partnership practitioners' -
 - (a) name;
 - (b) profession;
 - (c) registered category;
 - (d) speciality or subspeciality or field of professional practice (if any);
 - (e) registered qualifications or other academic qualifications or honorary degrees in abbreviated form;
 - (f) registration number;
 - (g) addresses (including email address);
 - (h) telephone and fax numbers;
 - (i) business hours;
 - (j) practice code number;
 - (k) exemption from registration in terms of section 54A of the Act; and
 - (l) dispensing licence number (if any).

- (3) A practitioner shall not use prescription forms or envelopes on which the name or address of a pharmacist is printed.

Naming of a practice

5. (1) A practitioner shall use his or her own name or the name of a registered practitioner or practitioners with whom he or she is in partnership or with whom he or she practises as a juristic person, as a name for his or her private practice.
- (2) A practitioner referred to in subrule (1) may retain the name of such private practice even if another practitioner, partner of such partnership or member of such juristic person is no longer part of such private practice: Provided that the express consent of the past practitioner or, in the case of a deceased

practitioner the consent of the executor of his or her estate or his or her next-of-kin, has been obtained.

- (3) A practitioner shall not use, in the name of his or her private practice, the expression "hospital", "clinic" or "institute" or any other expression which may give the impression that such private practice forms part of, or is in association with, a hospital, clinic or institute.

Itinerant practice

6. A practitioner may conduct a regularly recurring itinerant practice at a place where another practitioner is established if, in such itinerant practice, such practitioner renders the same level of service to patients, at the same fee as the service which he or she would render in the area in which he or she is conducting a resident practice.

Fees and commission

7. (1) A practitioner shall not accept commission or any material consideration, (monetary or otherwise) from a person or from another practitioner or institution in return for the purchase, sale or supply of any goods, substances or materials used by him or her in the conduct of his or her professional practice.
- (2) A practitioner shall not pay commission or offer any material consideration, (monetary or otherwise) to any person for recommending patients.
- (3) A practitioner shall not offer or accept any payment, benefit or material consideration (monetary or otherwise) which is calculated to induce him or her to act or not to act in a particular way not scientifically, professionally or medically indicated or to under-service, over-service or over-charge patients.
- (4) A practitioner shall not share fees with any person or with another practitioner who has not taken a commensurate part in the services for which such fees are charged.
- (5) A practitioner shall not charge or receive fees for services not personally rendered, except for services rendered by another practitioner in his or her employment or with whom he or she is associated as a partner, shareholder or locum tenens.
- (6) A practitioner shall explain to the patients the benefits, costs and consequences associated with each service option offered.

Partnership and juristic persons

8. (1) A practitioner may practise in partnership or association with or employ only a practitioner who is registered under the Act and who is not prohibited under any of the annexures to these rules or any ethical rulings from entering into such partnership or association or being so employed: Provided that, in the case of employment, the practitioner so employed either provides a supportive

health care service to complete or supplement the employing practitioner's healthcare or treatment intervention or is in the same professional category as the employing practitioner.

- (2) A practitioner shall practise in or as a juristic person who is exempted from registration in terms of section 54A of the Act only if such juristic person complies with the conditions of such exemption.
- (3) A practitioner shall practise in a partnership, association or as a juristic person only within the scope of the profession in respect of which he or she is registered under the Act.
- (4) A practitioner shall not practise in any other form of practice which has inherent requirements or conditions that violate or potentially may violate one or more of these rules or an annexure to these rules.

Sharing of Rooms

8. A practitioner shall not share his or her rooms with a person or entity not registered in terms of the Act.

Covering

9. (1) A practitioner shall employ as a professional assistant or locum tenens, or in any other contractual capacity and, in the case of locum tenens for a period not exceeding six months, only a person -
 - (a) who is registered under the Act to practise in independent practice;
 - (b) whose name currently appears on the register kept by the registrar in terms of section 18 of the Act; and
 - (c) who is not suspended from practising his or her profession.
- (2) A practitioner shall help or support only a person registered under the Act, the Pharmacy Act, 1974 (Act No. 53 of 1974), the Nursing Act, 1978 (Act No. 50 of 1978), the Social Service Professions Act, 1978 (Act No. 110 of 1978), the Dental Technicians Act, 1979 (Act No. 19 of 1979), or the Allied Health Professions Act, 1982 (Act No. 63 of 1982), if the professional practice or conduct of such person is legal and within the scope of his or her profession.

Supersession

10. A practitioner shall not supersede or take over a patient from another practitioner if he or she is aware that such patient is in active treatment of another practitioner, unless he or she –
 - (a) takes reasonable steps to inform the other practitioner that he or she has taken over the patient at such patient's request; and
 - (b) establishes from the other practitioner what treatment such patient previously received, especially what medication, if any, was prescribed to such patient

and in such case the other practitioner shall be obliged to provide such required information.

Impeding a patient

11. A practitioner shall not impede a patient, or in the case of a minor, the parent or guardian of such minor, from obtaining the opinion of another practitioner or from being treated by another practitioner.

Professional reputation of colleagues

12. A practitioner shall not cast reflections on the probity, professional reputation or skill of another person registered under the Act or any other Health Act.

Professional confidentiality

13. (1) A practitioner shall divulge verbally or in writing information regarding a patient which he or she ought to divulge only -
 - (a) in terms of a statutory provision;
 - (b) at the instruction of a court of law; or
 - (c) where justified in the public interest.
- (2) Any information other than the information referred to in subrule (1) shall be divulged by a practitioner only –
 - (a) with the express consent of the patient;
 - (b) in the case of a minor under the age of 12 years, with the written consent of his or her parent or guardian; or
 - (c) in the case of a deceased patient, with the written consent of his or her next-of-kin or the executor of such deceased patient's estate.

Retention of human organs

14. (1) A practitioner shall only for research, educational, training or prescribed purposes retain the organs of a deceased person during an autopsy.
- (2) The retention of organs referred to in subrule (1) shall be subject –
 - (a) to the express written consent given by the patient concerned during his or her lifetime;
 - (b) in the case of a minor under the age of 14 years, to the written consent of such minor's parent or guardian; or

- (c) in the case of a deceased patient who had not previously given such written consent, to the written consent of his or her next-of-kin or the executor of his or her estate.

Signing of official documents

- 15. A student, intern or practitioner who, in the execution of his or her professional duties, signs official documents relating to patient care, such as prescriptions, certificates (excluding death certificates), patient records, hospital or other reports, shall do so by signing such document next to his or her initials and surname printed in block letters.

Certificates and reports

- 16. (1) A practitioner shall grant a certificate of illness only if such certificate contains the following information –
 - (a) the name, address and qualification of such practitioner;
 - (b) the name of the patient;
 - (c) the employment number of the patient (if applicable);
 - (d) the date and time of the examination;
 - (e) whether the certificate is being issued as a result of personal observations by such practitioner during an examination, or as a result of information which has been received from the patient and which is based on acceptable medical grounds;
 - (f) a description of the illness, disorder or malady in layman's terminology with the informed consent of the patient: Provided that if such patient is not prepared to give such consent, the practitioner shall merely specify that, in his or her opinion based on an examination of such patient, such patient is unfit to work;
 - (g) whether the patient is totally indisposed for duty or whether such patient is able to perform less strenuous duties in the work situation;
 - (h) the exact period of recommended sick leave;
 - (i) the date of issue of the certificate of illness; and
 - (j) the initial and surname in block letters and the registration number of the practitioner who issued the certificate.
- (2) A certificate of illness referred to in subrule (1) shall be signed by a practitioner next to his or her initials and surname printed in block letters.
- (3) If preprinted stationery is used, a practitioner shall delete words which are not applicable.

- (4) A practitioner shall issue a brief factual report to a patient where such patient requires information concerning himself or herself.

Issuing of prescriptions

17. (1) A practitioner authorized in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), to prescribe medicines shall issue typewritten, handwritten, computer-generated, pre-typed, pre-printed or standardized prescriptions for medicine scheduled in Schedules 1, 2, 3 and 4 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), subject thereto that such prescriptions may be issued only under his or her personal and original signature.
- (2) A practitioner authorized in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), to prescribe medicines shall issue handwritten prescriptions for medicine scheduled in Schedules 5, 6, 7 and 8 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), under his or her personal and original signature.

Professional appointments

18. (1) A practitioner shall accept a professional appointment or employment from employers approved by the council only in accordance with a written contract of appointment or employment which is drawn up on a basis which is in the interest of the public and the profession.
- (2) A written contract of appointment or employment referred to in subrule (1) shall be made available to the council at its request.

Secret remedies

19. A practitioner shall in the conduct and scope of his or her practice, use only –
- (a) a form of treatment, apparatus or health technology which is not secret and which is not claimed to be secret; and
 - (b) an apparatus or health technology which proves upon investigation to be capable of fulfilling the claims made in regard to it.

Defeating or obstructing the council or board in the performance of its duties

20. A practitioner shall at all times cooperate and comply with any lawful instruction, directive or process of the council, a board, a committee of such board or an official of council and in particular, shall be required, where so directed to –
- (a) respond to correspondence and instructions from the council, such board, a committee of such board or an official of council within the stipulated time frames; and
 - (b) attend consultation at the time and place stipulated by the council, such board, a committee of such board or an official of council.

Performance of professional acts

21. A practitioner shall perform, except in an emergency, only a professional act -
- (a) for which he or she is adequately educated, trained and sufficiently experienced; and
 - (b) under proper conditions and in appropriate surroundings.

Exploitation

22. A practitioner shall not permit himself or herself to be exploited in any manner.

Medicine and medical devices

23. (1) A practitioner shall not participate in the manufacture for commercial purposes, or in the sale, advertising or promotion of any medicine or medical device or in any other activity that amounts to selling medicine or medical devices to the public or keeping an open shop or pharmacy.
- (2) A practitioner shall not engage in or advocate the preferential use or prescription of any medicine or medical device which, save for the valuable consideration he or she may derive from such preferential use or prescription, would not be clinically appropriate or the most cost-effective option.
- (3) The provisions of subrules (1) and (2) shall not prohibit a practitioner from -
- (a) owning shares in a listed company;
 - (b) manufacturing or marketing medicines whilst employed by a pharmaceutical concern;
 - (c) whilst employed by a pharmaceutical concern in any particular capacity, performing such duties as are normally in accordance with such employment; or
 - (d) dispensing in terms of a licence issued in terms of the Medicines and Related Substances Act, 1965.
- (4) A practitioner referred to in subrule (3) shall display a conspicuous notice in his or her waiting room and also duly inform his or her patient about the fact that he or she -
- (a) owns shares or has a financial interest in a listed public company that manufactures or markets the medicine or medical device prescribed for that patient; or
 - (b) is in the employ of or contractually engaged by the pharmaceutical or medical device company that manufactures such medicine or medical device,

and shall, subject to subrule (5), obtain the patient's informed written consent prior to prescribing such medicine or medical device for that patient."; and

- (5) A practitioner may prescribe or supply medicine or a medical device to a patient: Provided that such practitioner has ascertained the diagnosis of the patient concerned through a personal examination of the patient or by virtue of a report by another practitioner under whose treatment the patient is or has been and such medicine or medical device is clinically indicated, taking into account the diagnosis and the individual prognosis of the patient, and affords the best possible care at a cost-effective rate compared to other available medicines or medical devices and the patient is informed of such other available medicines or medical devices,
- (6) In the case of a patient with a chronic disease the provision of subrule (5) shall not apply.

Financial interests in hospitals

23A. A practitioner may have a direct or indirect financial interest or shares in a hospital or any other health care institution: Provided that -

- (a) such interests or shares are purchased at market-related prices in arm's length transactions;
- (b) the purchase transaction or ownership of such interest or shares does not impose conditions or terms upon the practitioner that will detract from the good, ethical and safe practice of his or her profession;
- (c) the returns on investment or payment of dividends is not based on patient admissions or meeting particular targets in terms of servicing patients;
- (d) such practitioner does not over-service patients and to this end establishes appropriate peer review and clinical governance procedures for the treatment and servicing of his or her patients at such hospital or health care institution;
- (e) such practitioner does not participate in the advertising or promotion of the hospital or health care institution, or in any other activity that amounts to such advertising or promotion;
- (f) such practitioner does not engage in or advocate the preferential use of such hospital or health care institution;
- (g) the purchase agreement is approved by the council based on the criteria listed in paragraphs (a) to (f) above; and

- (h) such practitioner annually submit a report to the council indicating the number of patients referred by him or her or his or her associates or partners to such hospital or health care institution and the number of patients referred to other hospitals in which he or she or his or her associates or partners hold no shares.

Referral of patients to hospitals

24. (1) A practitioner who has a direct or indirect financial interest or shares in a private clinic or hospital shall refer a patient to such clinic or hospital only if a conspicuous notice is displayed in his or her waiting room indicating that he or she has a financial interest or shares in that clinic or hospital and the patient is duly informed about the fact that the practitioner has an interest or shares in the clinic or hospital to which the patient is referred and the patient's informed written consent is obtained prior to such referral.
- (2) Deleted
- (3) Deleted
- (4) Deleted
- (5) Deleted
- (6) A practitioner may admit a patient to such private clinic or hospital: Provided that such practitioner -
- (a) has ascertained the diagnosis of the patient concerned through a personal examination of such patient or by virtue of a report by another practitioner under whose treatment such patient is or has been;
 - (a) has informed such patient that such admission in such private clinic or hospital was necessary for his or her treatment; and
 - (b) has obtained such patient's consent for admission to such private clinic or hospital.

Reporting of impairment or of unprofessional, illegal or unethical conduct

25. (1) A student, intern or practitioner shall -
- (a) report impairment in another student, intern or practitioner to the board if he or she is convinced that such student, intern or practitioner is impaired;
 - (b) report his or her own impairment or suspected impairment to the board concerned if he or she is aware of his or her own impairment or has been publicly informed, or has been seriously advised by a colleague to act appropriately to obtain help in view of an alleged or established impairment, and

- (c) report any unprofessional, illegal or unethical conduct on the part of another student, intern or practitioner.

Research, development and use of chemical, biological and nuclear capabilities

- 26. (1) A practitioner who is or becomes involved in research, development or use of defensive chemical, biological or nuclear capabilities shall obtain prior written approval from the board concerned to conduct such research, development or use.
- (2) In applying for written approval referred to in subrule (1), such practitioner shall provide the following information to the board concerned:
 - (a) Full particulars of the nature and scope of such research, development or use;
 - (b) whether the clinical trials pertaining to such research have been passed by a professionally recognized research ethics committee;
 - (c) that such research, development or use is permitted in terms of the provisions of the World Medical Association's Declaration on Chemical and Biological Weapons; and
 - (d) that such research, development or use is permitted in terms of the provisions of the applicable international treaties or conventions to which South Africa is a signatory.

Multiple registration

- 27. A health practitioner who holds registration with more than one statutory council or professional board or in one or more categories within the same professional board shall at all times ensure that -
 - (a) no conflict of interest arises from such multiple registration in the rendering of health services to patients;
 - (b) patients are clearly informed at the start of the consultation of the profession in which the practitioner is acting;
 - (c) informed consent regarding the profession referred to in paragraph (b) is obtained from the said patient;
 - (d) patients are not consulted in more than one capacity or charged fees based on more than one such consultation; and

- (e) no patients may be serviced by the same health practitioner in more than one capacity
- (f) the ethical rules applicable at a given moment to the profession in which the practitioner is acting, are strictly adhered to.

Main responsibilities of health practitioners

27A. A practitioner shall at all times

- (a) act in the best interests of his or her patients;
- (b) respect patient confidentiality, privacy, choices and dignity;
- (c) maintain the highest standards of personal conduct and integrity;
- (d) provide adequate information about the patient's diagnosis, treatment options and alternatives, costs associated with each such alternative and any other pertinent information to enable the patient to exercise a choice in terms of treatment and informed decision-making pertaining to his or her health and that of others;
- (e) keep his or her professional knowledge and skills up to date;
- (f) maintain proper and effective communication with his or her patients and other professionals;
- (g) except in an emergency, obtain informed consent from a patient or, in the event that the patient is unable to provide consent for treatment himself or herself, from his or her next of kin; and
- (h) keep accurate patient records.

Repeal

28. The Rules Specifying the Acts or Omissions in respect of which Disciplinary Steps may be taken by a Professional Board and the Council, published under Government Notice No. R. 2278 of 3 December 1976 and Government Notice No. R. 1379 of 12 August 1994, as amended by Government Notice No. R. 1405 of 22 December 2000 are hereby repealed.

ANNEXURES**ANNEXURE 1****PROFESSIONAL BOARD FOR DENTAL THERAPY AND ORAL HYGIENE****RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE PROFESSIONS OF
DENTAL THERAPY,****ORAL HYGIENE AND DENTAL ASSISTANTS**

A dental therapist, student in dental therapy, an oral hygienist, a student in oral hygiene and a dental assistant shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such dental therapist, student in dental therapy, oral hygienist and student in oral hygiene to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by dental therapist**1. A dental therapist –**

- (a) shall confine himself or herself to clinical diagnosis and practice in the field of dental therapy in which he or she was educated and trained and in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
- (b) shall communicate and co-operate with dentists, dental specialists, dental therapists and other registered practitioners in the diagnosis and treatment of a patient;
- (c) shall not conduct a private practice unless he or she has met the requirements of the board and practised for at least one year under the control and supervision of a dentist or another dental therapist approved by the board;
- (d) shall refer the following cases to a dentist or dental specialist for treatment:
 - (i) Pulpal exposure, excluding the emergency treatment thereof;
 - (ii) impacted teeth; and

- (iii) oral diseases and dental abnormalities, such as tumours, mucosal diseases, developmental defects and infections;
- (e) shall not remove the roots of teeth by any way other than the use of hand instruments or make any incision into the soft tissues during such removal; and
- (f) shall not manufacture or repair dentures or other dental appliances which involve the taking of impressions.

Performance of professional acts by oral hygienist

2. *An oral hygienist –*

- (a) shall confine himself or herself to clinical practice in the field of oral hygiene in which he or she was educated and trained and in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
- (b) shall communicate and cooperate with dentists, dental therapists and other registered practitioners in the treatment of a patient; and
- (c) shall not conduct a private practice unless he or she has met the requirements of the board.

Performance of professional acts by dental assistant

- 3. A dental assistant shall perform professional acts only under the supervision of a registered practitioner and shall limit such acts to acts directly related to his or her education and training in dental assistance.

Performance of professional acts by student in dental therapy

- 4. A student in dental therapy shall perform professional acts only under the supervision of a registered practitioner and shall limit such acts to acts directly related to his or her education and training in dental therapy.

Performance of professional acts by student in oral hygiene

5. A student in oral hygiene shall perform professional acts only under the supervision of a dentist, dental therapist, an oral hygienist or other registered practitioner and shall limit such acts to acts directly related to his or her education and training in oral hygiene.

ANNEXURE 2**PROFESSIONAL BOARD FOR DIETETICS****RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE PROFESSION OF
DIETETICS**

A dietitian, food service manager, nutritionist, student in dietetics, student in food service management and student in nutrition shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such dietitian, food service manager, nutritionist, student in dietetics, student in food service management and student in nutrition to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by a dietitian

1. A dietitian –
 - (a) shall confine himself or herself to the performance of professional acts in the field of dietetics in which he or she was educated and trained and in which he or she has gained experience; and
 - (b) shall not fail to communicate and cooperate with other registered practitioners in the treatment of a patient.

Performance of professional acts by assistant dietitian

2. An assistant dietitian -
 - (a) shall perform professional acts in dietetics only under the supervision of a dietitian or nutritionist;
 - (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in dietetics; and
 - (c) shall not conduct a private practice.

Performance of professional acts by food service manager

3. A food service manager shall confine himself or herself to the performance of professional acts in the field of food service management in which he or she was educated and trained and in which he or she has gained experience.

Performance of professional acts by nutritionist

4. A nutritionist –

- (a) shall perform professional acts only under the supervision of a registered practitioner and shall limit such acts to acts directly related to his or her education and training; and
- (b) shall not conduct a therapeutic private practice.

Performance of professional acts by assistant nutritionist

5. An assistant nutritionist -
- (a) shall perform professional acts in nutrition only under the supervision of a nutritionist or dietitian;
 - (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training; and
 - (c) shall not conduct a private practice.

Performance of professional acts by student in dietetics

6. A student in dietetics shall perform professional acts only under the supervision of a registered practitioner and shall limit such acts to acts directly related to his or her education and training.

Performance of professional acts by student in food service management

7. A student in food service management shall perform professional acts only under the supervision of a registered practitioner and shall limit such acts to acts directly related to his or her education and training.

Performance of professional acts by student in nutrition

8. A student in nutrition shall perform professional acts only under the supervision of a registered practitioner and shall limit such acts to acts directly related to his or her education and training.

ANNEXURE 3

PROFESSIONAL BOARD FOR EMERGENCY CARE PRACTITIONERS RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE PROFESSION OF EMERGENCY CARE

A basic ambulance assistant, an emergency care assistant, ambulance emergency assistant, operational emergency orderly, a paramedic student basic ambulance assistant, student emergency care assistant, student ambulance emergency assistant or student paramedic shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such basic ambulance assistant, emergency care assistant, ambulance emergency assistant, operational emergency orderly and paramedic or student basic ambulance assistant, student emergency care assistant, student ambulance emergency assistant, student operational emergency orderly or student paramedic to comply with the additional rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by basic ambulance assistant, emergency care assistant, ambulance emergency assistant, operational emergency orderly or paramedic

1. Notwithstanding the provisions of rule 21, a basic ambulance assistant, an emergency care assistant, ambulance emergency assistant, operational emergency orderly or a paramedic –
 - (a) shall not perform any professional act or exercise any capability in respect of any incident, other than the acts set out in the relevant protocol or annexure to such protocol approved by the board; and
 - (b) shall not hand over the responsibility for the treatment of a patient to any person who is less qualified or experienced than himself or herself, unless such basic ambulance assistant, emergency care assistant, ambulance emergency assistant, operational emergency care orderly or paramedic assumes full responsibility for the acts falling within his or her scope of practice.

Performance of professional acts by student basic ambulance assistant, student emergency care assistant, student ambulance emergency assistant or student paramedic

2. A student basic ambulance assistant shall perform professional acts only under the supervision of a registered emergency care assistant and, in the case of a student emergency care assistant, student ambulance emergency assistant, student operational emergency care orderly or student paramedic only under the supervision of a medical practitioner or a paramedic and shall limit such acts to acts directly related to his or her education and training.

ANNEXURE 4

PROFESSIONAL BOARD FOR ENVIRONMENTAL HEALTH PRACTITIONERS RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE PROFESSION OF ENVIRONMENTAL HEALTH

An environmental health practitioner, environmental health assistant, a food inspector and a student in environmental health shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such environmental health practitioner, environmental health assistant, food inspector and student in environmental health to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by environmental health practitioner

- 1. An environmental health practitioner –**
 - (a) shall confine himself or herself to practising in the field of environmental health in which he or she was educated and trained; and
 - (b) shall not conduct a private practice without meeting the requirements of the board.

Performance of professional acts by environmental health assistant

- 2. An environmental health assistant –**
 - (a) shall perform professional acts only under supervision of an environmental health practitioner;
 - (b) shall confine himself or herself to practising in the field of environmental health in which he or she was educated and trained; and
 - (c) shall not conduct a private practice.

Performance of professional acts by food inspector

3. A food inspector –

- (a) shall perform professional acts only under the supervision of an environmental health practitioner;
- (b) shall confine himself or herself to practising in the field of environmental health in which he or she was educated and trained; and
- (c) shall not conduct a private practice.

Performance of professional acts by student in environmental health

- 4. A student in environmental health shall perform professional acts only under the supervision of an environmental health practitioner.**

ANNEXURE 5**PROFESSIONAL BOARD FOR MEDICAL TECHNOLOGY****RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE PROFESSION OF
MEDICAL TECHNOLOGY**

A medical technologist, medical technician, an intern medical technologist and a student in biomedical technology shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such medical technologist, medical technician, intern medical technologist and student in biomedical technology to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by medical technologist

1. A medical technologist –
 - (a) shall confine himself or herself to practising in the specific discipline of medical technology in which he or she was educated, trained and registered;
 - (b) shall not conduct a private practice without obtaining -
 - (i) postgraduate experience of at least two years; and
 - (ii) prior written approval from the board; and
 - (c) shall, if he or she does not comply with the provisions of paragraph (b), perform professional acts only under the direction of a medical practitioner or medical scientist who is registered in the relevant discipline: Provided that this prohibition shall apply only to acts excluded, as determined by the board.

Performance of professional acts by medical technician

2. A medical technician –
 - (a) shall confine himself or herself to practising in the specific discipline of medical technology in which he or she was educated, trained and registered;
 - (b) shall perform professional acts only under the supervision of a medical practitioner or medical technologist who is registered in the relevant discipline; and

- (c) shall not conduct a private practice.

Performance of professional acts by intern medical technologist

- 3. An intern medical technologist –
 - (a) shall perform professional acts only under the supervision of a practitioner who is registered in the relevant discipline;
 - (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training as part of the formal internship in his or her discipline of study;
 - (c) shall not conduct a private practice; and
 - (d) if he or she has completed his or her internship, shall not perform any professional acts until he or she has satisfied all the academic requirements for registration as a medical technologist and has been registered as such.

Performance of professional acts by student in medical technology

- 4. A student in medical technology –
 - (a) shall perform professional acts only under the supervision of a practitioner who is registered in the relevant discipline; and
 - (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in his or her discipline of study.

Performance of professional acts by laboratory assistant

- 5. A laboratory assistant –
 - (a) shall confine himself or herself to performing acts in the specific discipline of medical technology in which he or she is educated, trained and registered;
 - (b) shall perform professional acts only under the supervision of a medical practitioner or medical technologist who is registered in the relevant discipline; and
 - (c) shall not conduct a private practice.

ANNEXURE 6**MEDICAL AND DENTAL PROFESSIONS BOARD****RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE MEDICAL AND DENTAL PROFESSIONS**

A medical practitioner, dentist, medical specialist, dental specialist, biomedical engineer, clinical biochemist, genetic counsellor, medical biological scientist, medical physicist, an intern in biomedical engineering, intern in clinical biochemistry, intern in genetic counselling, intern in medical biological science and intern in medical physics shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such medical practitioner, dentist, medical specialist, dental specialist, biomedical engineer, clinical biochemist, genetic counsellor, medical biological scientist, medical physicist, intern in biomedical engineering, intern in clinical biochemistry, intern in genetic counselling, intern in medical biological science and intern in medical physics to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by medical practitioner or medical specialist

1. A medical practitioner or medical specialist -
 - (a) shall perform professional acts only in the field of medicine in which he or she was educated and trained and in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
 - (b) shall not fail to communicate and cooperate with medical practitioners, medical specialists and other health practitioners in the diagnosis and treatment of a patient; and
 - (c) shall not sign official documents such as reports, certificates or prescriptions unless his or her name is printed next to his or her signature.

Performance of professional acts by dentist or dental specialist

2. A dentist or dental specialist –
 - (a) shall perform professional acts only in the field of dentistry in which he or she was educated and trained and in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
 - (b) shall not fail to communicate and cooperate with dentists, dental specialists and other health practitioners in the diagnosis and treatment of a patient; and
 - (c) shall not sign official documents such as reports, certificates or prescriptions unless his or her name is printed next to his or her signature.

Partnerships and juristic persons

3. (1) Where a patient is seen -
 - (a) by both a medical specialist or a dental specialist and a medical practitioner or a dentist practising as specified in rule 8(3), such specialist and medical practitioner or dentist shall charge the fees applicable to either the medical practitioner or the dentist and not those applicable to a medical specialist or a dental specialist; and
 - (b) by a medical specialist or a dental specialist only, the fees applicable to such specialist may be charged.

- (2) The provisions in rule 8 (3) shall be limited in that -
 - (a) a medical specialist who practises in one of the prescribed related specialities in medical pathology shall be excluded from the concession to form an incorporated practice in terms of section 54A, or to form a partnership or association with a medical practitioner, a medical specialist or another practitioner who does not practise in one of the related specialities in medical pathology;
 - (b) a medical specialist who practises in diagnostic radiology shall be excluded from the concession to form an incorporated practice in terms of section 54A, or to form a partnership or association with a medical

practitioner, medical specialist or another practitioner who does not practise in the speciality diagnostic radiology;

- (c) the only exception to the restriction pertaining to specialities in medical pathology referred to in paragraph (a) hereof shall be that a pathologist shall be permitted to form an incorporated practice, partnership or association with a medical technologist registered in the relevant discipline in view of the fact that the said two professions are related to each other in terms of the nature of the field of professional practice; and
- (d) the only exception to the restriction pertaining to radiology referred to in paragraph (b) hereof shall be that a radiologist shall be permitted to form an incorporated practice, partnership or association with a nuclear physician or a radiographer registered in the relevant discipline in view of the fact that the said two medical professions are related to each other in terms of the nature of their field of professional practice.

Medical specialist and dental specialist

- 4. A medical specialist and a dental specialist shall adhere to the Regulations relating to the Specialities and Subspecialities in Medicine and Dentistry, published under Government Notice No. R. 590 of 29 June 2001.**

Performance of professional acts by biomedical engineer, clinical biochemist, genetic counsellor, medical biological scientist, medical physicist

- 5. A biomedical engineer, a clinical biochemist, a genetic counsellor, a medical biological scientist and a medical physicist –
 - (a) shall perform professional acts only at the request of and in consultation with a medical practitioner or dentist;
 - (b) shall perform professional acts directly related to the treatment or diagnosis of a patient, in close cooperation with the medical practitioner or dentist concerned with the diagnosis or treatment of such patient; and

- (c) shall not sign official documents such as reports, certificates or prescriptions, unless his or her name is printed next to his or her signature.

Performance of professional acts by intern in medicine

- 6. An intern in medicine -
 - (a) shall perform acts as part of a structured internship training programme at an approved facility only under the supervision of a medical practitioner as prescribed for this purpose and in accordance with the guidelines of the board;
 - (b) shall limit acts referred to in (a) to acts related to his or her education and training as part of a structured internship programme;
 - (c) shall not conduct a private practice;
 - (d) shall not act as a locum or perform professional acts in a private practice;
 - (e) if he or she has completed his or her internship, shall not perform any professional act until he or she has satisfied all the academic requirements for registration as a medical practitioner and has been registered as such; and
 - (f) shall not sign official documents such as reports, certificates or prescriptions, unless his or her name is printed next to his or her signature.

Performance of professional acts by interns in biomedical engineering, clinical biochemistry, genetic counselling, medical biological science or medical physics

- 7. An intern in biomedical engineering, clinical biochemistry, genetic counselling, medical biological science or medical physics –
 - (a) shall perform professional acts as part of a structured internship training programme at an approved facility only under the supervision of a practitioner as prescribed for this purpose and in accordance with the guidelines of the board;
 - (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training as part of a structured internship programme in his or her discipline of study;
 - (c) shall not conduct a private practice;

- (d) shall not act as a locum or perform professional acts in a private practice;
- (e) if he or she has completed his or her internship, shall not perform any professional act until he or she
has satisfied all the academic requirements for registration as a medical scientist and has
been registered as such; and
- (f) shall not sign official documents such as reports, certificates or prescriptions, unless his or her
name is printed next to his or her signature.

Performance of professional acts by student in medicine or dentistry

- 8. A student in medicine or dentistry -
 - (a) shall perform professional acts only under the supervision of a practitioner approved for this purpose by the board;
 - (b) shall limit acts referred to in (a) to acts related to his or her education and training;
 - (c) shall not conduct a private practice; and
 - (d) shall not act as a locum or perform professional acts in a private practice.

ANNEXURE 7**PROFESSIONAL BOARD FOR OCCUPATIONAL THERAPY AND
MEDICAL ORTHOTICS OR PROSTHETICS****RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE PROFESSION OF
OCCUPATIONAL THERAPY AND MEDICAL ORTHOTICS OR PROSTHETICS**

An occupational therapist, occupational therapy assistant, occupational therapy technician, a student in occupational therapy, an arts therapist, student in arts therapy, medical orthotist or prosthetist, an orthopaedic footwear technician, assistant medical orthotist or prosthetist, leatherworker and student in medical orthotics or prosthetics shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such occupational therapist, occupational therapy assistant, occupational therapy technician, student in occupational therapy, arts therapist, student in arts therapy, medical orthotist or prosthetist, orthopaedic footwear technician, assistant medical orthotist or prosthetist, leatherworker and student in medical orthotics or prosthetics to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by an occupational therapist**1. An occupational therapist –**

- (a) shall perform professional acts only in the field of occupational therapy in which he or she was educated and trained and in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
- (b) shall communicate and cooperate with medical practitioners and other registered health practitioners in the diagnosis and treatment of a patient; and
- (c) in private practice may not employ any person as an occupational therapy assistant or an occupational therapy technician without the prior written approval of the board: Provided that this prohibition shall not apply in the case of a full-time or part-time appointment in the public service.

Performance of professional acts by occupational therapy assistant

2. An occupational therapy assistant –

- (a) shall perform professional acts only under the supervision of an occupational therapist or appropriately qualified registered practitioner: Provided that in the case of supervision under an appropriately qualified registered practitioner, such supervision shall not extend for a period of more that six months;
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in his or her discipline of study;
- (c) shall not accept employment without the prior written approval of the board: Provided that this prohibition shall not apply in the case of a full-time or part-time appointment in the public service; and
- (d) shall not conduct a private practice.

Performance of professional acts by occupational therapy technician

3. An occupational therapy technician –

- (a) shall perform professional acts only under the supervision of an occupational therapist or an appropriately qualified registered practitioner: Provided that in the case of supervision under an appropriately qualified registered practitioner, such supervision shall not extend for a period of more than six months;
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in his or her discipline of study;
- (c) shall not accept an appointment without the prior written approval of the board: Provided that this prohibition shall not apply in the case of a full-time or part-time appointment in the public service; and
- (d) shall not conduct a private practice.

Performance of professional acts by student in occupational therapy

4. A student in occupational therapy –

- (a) shall perform professional acts only under the supervision of an occupational therapist or appropriately qualified registered practitioner: Provided that in the case of supervision under an appropriately qualified registered practitioner, such supervision shall not extend for a period of more than six months; and
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in occupational therapy.

Performance of professional acts by arts therapist

5. An arts therapist –

- (a) shall perform professional acts only in the specific registered category of arts therapy;
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
- (c) shall not fail to communicate and cooperate, where appropriate, with medical practitioners and other registered health practitioners in the diagnosis and treatment of a patient; and
- (d) shall not employ an occupational therapy assistant or an occupational therapy technician without the prior written approval of the board: Provided that this prohibition shall not apply in the case of a full-time or part-time appointment in the public service.

Performance of professional acts by student in arts therapy

6. A student in arts therapy –

- (a) shall perform professional acts only under the supervision of an arts therapist; and
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in the specific category of arts therapy.

Performance of professional acts by medical orthotist or prosthetist**7. A medical orthotist or prosthetist –**

- (a) shall perform professional acts only in the field of medical orthotics or prosthetics;
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
- (c) shall not fail to communicate and cooperate, where appropriate, with medical practitioners and other registered health practitioners in the diagnosis and treatment of a patient; and
- (d) shall not give any treatment in connection with or advice or assistance preparatory to or for the purpose of the manufacture, repair, supply, fitting or fixing of artificial limbs or other similar assistive devices, whether for gain or not, where such devices are supplied or are to be supplied to the patient by a person who is not a medical orthotist or prosthetist.

Performance of professional acts by orthopaedic footwear technician**8. An orthopaedic footwear technician –**

- (a) shall perform professional acts only under the supervision of a medical orthotist or prosthetist;
- (b) shall not conduct a private practice; and
- (c) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in his or her discipline of study.

Performance of professional acts by assistant medical orthotist or prosthetist and leatherworker

9. An assistant medical orthotist or prosthetist and leatherworker –

- (a) shall perform professional acts only under the supervision of a medical orthotist or prosthetist;
- (b) shall not conduct a private practice; and
- (c) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in his or her discipline of study

Performance of professional acts by student in medical orthotics or prosthetics

10. A student in medical orthotics or prosthetics –

- (a) shall perform professional acts only under the supervision of a medical orthotist or prosthetist; and
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in medical orthotics or prosthetics.

ANNEXURE 8

PROFESSIONAL BOARD FOR OPTOMETRY AND DISPENSING OPTICIANS RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE PROFESSION OF OPTOMETRY AND DISPENSING OPTICIANS

An optometrist, a student in optometry, dispensing optician and dispensing optician student shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such optometrist, student in optometry, dispensing optician and dispensing optician student to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by optometrist

1. (1) An optometrist –

- (a) shall provide only optometric services, including the prescription of spectacle lenses, contact lenses and visual aids or appliances. In cases where pathology of the visual system is detected or suspected, or where the patient cannot attain normal single or binocular vision with the aid of corrective lenses or other methods of correction, the optometrist should work in close collaboration with a medical practitioner who has received adequate education and training as approved by the board for this purpose; and
 - (b) shall , only in the treatment of a patient, use a scheduled substance subject to the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
- (2) Notwithstanding the requirements relating to the naming of practices referred to in rule 5, an optometrist may make use of a practice name: Provided that -
- (a) he or she obtains prior approval for the use of the practice name from the board;
 - (b) such name or the use thereof is not indecent, misleading or deceptive and is in keeping with the professional image or dignity of the profession and that such practice name does not claim prominence for a registered optometrist; and

- (c) the names of the responsible practitioners are displayed together with or alongside the practice name.

Performance of professional acts by student in optometry

2. A student in optometry –

- (a) shall perform professional acts only under the supervision of an optometrist or medical practitioner; and
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in optometry.

Performance of professional acts by dispensing optician

- 3.** A dispensing optician shall not dispense in any way spectacles to any person except on a prescription written and signed by a medical practitioner or an optometrist: Provided that this rule shall not apply to the repair or replacement of such spectacles or lenses or frames for such spectacles.

Performance of professional acts by dispensing optician student

4. A dispensing optician student –

- (a) shall perform professional acts only under the supervision of a dispensing optician, optometrist or medical practitioner; and
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her training in optical dispensing.

ANNEXURE 9

PROFESSIONAL BOARD FOR PHYSIOTHERAPY, PODIATRY AND BIODYNAMICS

RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE PROFESSION OF PHYSIOTHERAPY, PODIATRY AND BIODYNAMICS

A physiotherapist, physiotherapy assistant, student in physiotherapy, podiatrist, student in podiatry, biodynamicist and student in biodynamics shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such physiotherapist, physiotherapy assistant, student in physiotherapy, podiatrist, student in podiatry, biodynamicist and student in biodynamics to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by physiotherapist

1. A physiotherapist –

- (a) shall confine himself or herself to clinical diagnoses and practising in the field of physiotherapy in which he or she was educated and trained and in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
- (b) shall not fail to communicate and cooperate, where appropriate with medical practitioners in the diagnosis and treatment of a patient;
- (c) shall refer a patient to a practitioner when the patient's problems and needs are beyond the scope of physiotherapy; and
- (d) shall not employ a physiotherapy assistant without the prior written approval of the council: Provided that this prohibition shall not apply in the case of full-time or part-time employment in the public service.

Performance of professional acts by physiotherapy assistant

2. A physiotherapy assistant shall not accept an appointment in private practice without the prior written approval of the council: Provided that this prohibition shall not apply in the case of a full-time or part-time appointment in the public service.

Performance of professional acts by physiotherapy technician

3. A physiotherapy technician shall not accept an appointment in private practice without the prior written approval of the council: Provided that this prohibition shall not apply in the case of a full-time or part-time appointment in the public service.

Performance of professional acts by student in physiotherapy

4. **A student in physiotherapy –**
 - (a) shall perform professional acts pertaining to physiotherapy only under the supervision of a physiotherapist or a medical practitioner; and
 - (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in physiotherapy.

Performance of professional acts by podiatrist

5. **A podiatrist –**
 - (a) shall investigate and treat only disorders which fall within the scope of the profession of podiatry;
 - (b) shall, in the treatment of any person, use only medicines or surgery which have been specifically approved for that purpose by the board;
 - (c) shall administer local anaesthetic only for the purpose of relieving pain, the specific medicine for which shall have been approved by the board and the regulatory authority on medicines; and
 - (d) shall perform professional acts requiring general anaesthetic only in close collaboration with a medical practitioner.

Performance of professional acts by student in podiatry

6. **A student in podiatry –**
 - (a) shall perform professional acts pertaining to podiatry only under the

- supervision of a podiatrist or a medical practitioner; and
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in podiatry.

Performance of professional acts by biokineticist

7. A biokineticist –

- (a) shall confine himself or herself to functional and clinical diagnoses, and practising in the field of biokinetics in which he or she was educated and trained and in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
- (b) shall not fail to communicate and cooperate, where appropriate, with medical practitioners and other practitioners in the diagnosis and treatment of a patient; and
- (c) shall refer a patient to a practitioner when the patient's problems and needs are beyond the scope of biokinetics.

Performance of professional acts by student in biokinetics

8. A student in biokinetics –

- (a) shall perform professional acts pertaining to biokinetics only under the supervision of a biokineticist or a medical practitioner; and
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in biokinetics.

ANNEXURE 10**PROFESSIONAL BOARD FOR RADIOGRAPHY AND CLINICAL TECHNOLOGY
RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE PROFESSION OF
RADIOGRAPHY AND CLINICAL TECHNOLOGY**

A radiographer, an assistant radiographer, a radiation laboratory technologist, student in radiography, student radiation laboratory technologist, graduate clinical technologist or clinical technologist (registered prior to 1 April 2002), clinical technologist (registered after 31 March 2002), an assistant clinical technologist, electroencephalography technician, a student in clinical technology and a student electro-encephalography technician shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such radiographer, assistant radiographer, radiation laboratory technologist, student in radiography, student radiation laboratory technologist, graduate clinical technologist or clinical technologist (registered prior to 1 April 2002), clinical technologist (registered after 31 March 2002), assistant clinical technologist, electroencephalography technician, student in clinical technology and student electro-encephalography technician to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by radiographer

1. A radiographer –
 - (a) shall perform professional acts only at the written request and under the supervision of a practitioner approved by the board for such purpose: Provided that this prohibition shall not apply in respect of –
 - (i) acts pertaining to the profession of radiography determined by the board for such purpose;
 - (ii) a radiographer who complies with the conditions set by the board in this regard and who in the opinion of such board is competent to perform professional acts without supervision at the written request of such practitioner; and

- (iii) a request from such practitioner which in the opinion of the radiographer was based on good and sufficient grounds: Provided that such request was in writing and signed by the person making the request;
- (b) shall consult in regard to any work performed by him or her in his or her profession only with a practitioner approved by the board at whose instance such work was undertaken;
- (c) shall not interpret radiographical investigations, report thereon or furnish information in regard to any work performed by him or her in his or her profession to any person other than a practitioner approved by the board at whose request such work was undertaken; and
- (d) shall not in his or her practice exceed the limits of the category or categories in which he or she is registered.

Performance of professional acts by assistant radiographer

2. An assistant radiographer –

- (a) shall perform professional acts in radiography only under the supervision of a registered practitioner approved by the board or radiographer;
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in radiography;
- (c) shall not conduct a private practice; and
- (d) shall not perform any diagnostic X-ray examination in any place other than a hospital or facility in the public service or operated by the South African Chamber of Mines or such other facility as may be approved by the board for a specific purpose.

Performance of professional acts by radiation laboratory technologist**3. A radiation laboratory technologist -**

- (a) shall perform professional acts in radiation laboratory technology only under the supervision of a registered practitioner approved by the board or a radiographer;
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in radiation laboratory technology; and
- (c) shall not conduct a private practice.

Performance of professional acts by student in radiography**4. A student in radiography –**

- (a) shall perform professional acts in radiography only under the supervision of a registered practitioner approved by the board or a radiographer; and
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in radiography.

Performance of professional acts by student radiation laboratory technologist**5. A student radiation laboratory technologist –**

- (a) shall perform professional acts in radiation laboratory technology only under the supervision of a registered practitioner approved by the board or a radiographer; and
- (b) shall limit the acts referred to in paragraph (a) to acts directly related to his or her education and training in radiation laboratory technology.

Performance of professional acts by graduate clinical technologist or clinical technologist registered prior to 1 April 2002

6. A graduate clinical technologist or clinical technologist registered prior to 1 April 2002 –
- (a) shall confine himself or herself to the performance of professional acts in the field of clinical technology in which he or she was educated and trained and in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
 - (b) shall not fail to communicate and cooperate, where appropriate, with registered practitioners approved by the board in the treatment of a patient; and
 - (c) shall perform professional acts only in collaboration with a registered practitioner approved by the board or a specialist.

Performance of professional acts by clinical technologist qualified after 31 March 2002

7. A clinical technologist who qualified as such after 31 March 2002 –
- (a) shall perform professional acts only under the supervision of or in collaboration with a registered practitioner approved by the board or a specialist;
 - (b) shall confine himself or herself to the performance of professional acts in the field of clinical technology in which he or she was educated and trained and in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
 - (c) shall not conduct a private practice; and
 - (d) shall not fail to communicate and cooperate, where appropriate, with registered practitioners approved by the board in the treatment of a patient.

Performance of professional acts by assistant clinical technologist

8. **An assistant clinical technologist -**
- (a) shall perform professional acts only in collaboration with clinical technologists, specialists or practitioners approved by the board for such purpose;

- (b) shall confine himself or herself to the performance of professional acts in the field of clinical technology in which he or she was educated and trained and in which he or she has gained experience, regard being had to both the extent and the limits of his or her professional expertise;
- (c) shall not conduct a private practice; and
- (d) shall not fail to communicate and cooperate, where appropriate, with registered practitioners approved by the board in the treatment of a patient.

Performance of professional acts by electroencephalography technician

9. An electroencephalography technician –
- (a) shall perform professional acts only under the supervision of clinical technologists, specialists or practitioners approved by the board for such purpose;
 - (b) shall limit the acts referred to in paragraph (a) to acts related to his or her education and training in electroencephalography;
 - (c) shall not conduct a private practice; and
 - (d) shall not fail to communicate and cooperate, where appropriate, with registered practitioners approved by the board in the treatment of a patient.

Performance of professional acts by student in clinical technology

10. A student in clinical technology –
- (a) shall perform professional acts only under the supervision of clinical technologists, specialists or practitioners approved by the board for such purpose; and
 - (b) shall limit the acts referred to in paragraph (a) to acts related to his or her education and training in clinical technology.

Performance of professional acts by student electroencephalography technician

11. A student electroencephalography technician –

- (a) shall perform professional acts only under the supervision of clinical technologists, specialists or practitioners approved by the board for such purpose; and
- (b) shall limit the acts referred to in paragraph (a) to acts related to his or her education and training in electroencephalography technology.

ANNEXURE 11**PROFESSIONAL BOARD FOR SPEECH, LANGUAGE AND HEARING
PROFESSIONS****RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE SPEECH, LANGUAGE
AND HEARING PROFESSIONS**

A speech therapist, an audiologist, an audiometrician, a hearing aid acoustician, speech and hearing correctionist, speech and hearing community worker, speech and hearing assistant, student in speech profession, student in language profession and student in hearing profession shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such speech therapist, audiologist, audiometrician, hearing aid acoustician, speech and hearing correctionist, speech and hearing community worker, speech and hearing assistant, student in speech profession, student in language profession and student in hearing profession to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

Performance of professional acts by speech therapist or audiologist

1. A speech therapist or an audiologist -
 - (a) shall confine himself or herself to clinical diagnoses, and practising in the field of speech-language therapy or audiology in which he or she was educated and trained and in which he or she has gained experience, with due regard to both the extent and the limits of his or her professional expertise;
 - (b) shall not fail to communicate and cooperate, where appropriate, with medical practitioners and other practitioners in the diagnosis and treatment of a patient; and
 - (c) shall refer a patient to a practitioner or educational professional when the patient's problems and needs are beyond the scope of speech-language therapy or audiology.

Performance of professional acts by audiometrician

2. An audiometrician -

- (a) shall practice only in the appropriate fields in which he or she has been trained and in which he or she has gained experience, with due regard to both the extent and the limits of his or her professional expertise; and
- (b) shall perform any work in audiometry only -
 - (i) under the supervision of an audiologist; or
 - (ii) with the prior written approval of the board, under the direction and supervision of a medical practitioner or other practitioners approved by the board.

Performance of professional acts by hearing aid acoustician

3. A hearing aid acoustician -

- (a) shall confine himself or herself to practising in the appropriate fields in which he or she has been trained and in which he or she has gained experience, with due regard to both the extent and the limits of his or her professional expertise;
- (b) shall refer a patient to a practitioner when the patient's problem is beyond the scope of the practice of the hearing aid acoustician;
- (c) shall not diagnose a person's hearing ability;
- (d) shall not select and fit a hearing aid to children under the age of 10 years, or to persons with multiple handicaps; and
- (e) shall not affix his or her nameplate at the entrance of a pharmacy, unless he or she is also registered as a pharmacist.

Performance of professional acts by speech and hearing correctionist

4. A speech and hearing correctionist –

- (a) shall confine himself or herself to practising in the appropriate fields in which he or she has been trained and in which he or she has gained experience,

- with due regard to both the extent and the limits of his or her professional expertise;
- (b) shall not perform any speech or language therapy or audiology, except in a primary school, nursery school or school for the deaf or hearing impaired controlled by the government or the provincial Department of Education concerned or in such other institution as may be approved for this purpose by the board;
 - (c) shall not perform any speech or language therapy or audiology, in assessment and treatment clinics associated with education departments or other institutions, except under the direct supervision of a speech therapist or audiologist; and
 - (d) shall not conduct a private practice.

Performance of professional acts by speech and hearing community worker

- 5. A speech and hearing community worker –
 - (a) shall confine himself or herself to the appropriate fields in which he or she has been trained and in which he or she has gained experience, with due regard to both the extent and the limits of his or her professional expertise;
 - (b) shall not perform any speech or language and hearing community work, except when employed by an institution or establishment recognised by the board;
 - (c) shall not perform any speech or language and hearing community work in an institution or establishment where a speech therapist or audiologist is employed except under the direction of such speech therapist and/or audiologist;
 - (d) shall not perform any speech or language and hearing community work, except in consultation with a general medical practitioner or, in cases involving oral conditions, in consultation with a dentist;
 - (e) shall not perform any speech or language and hearing community work where supervision by a speech therapist and/or an audiologist is possible, or regard being had to geographical proximity where such supervision is not possible, in consultation with a speech therapist or an audiologist; and
 - (f) shall not conduct a private practice.

Performance of professional acts by speech and hearing assistant

6. A speech and hearing assistant –
- (a) shall confine himself or herself to practising in the appropriate fields in which he or she has been trained and in which he or she has gained experience, with due regard to both the extent and the limits of his or her professional expertise;
 - (b) shall perform professional acts only-
 - (i) under the direction and supervision or in the employment of a speech therapist or an audiologist in the health or education sectors; and
 - (ii) with the approval of the board under the direction and supervision of a general medical practitioner or other practitioner registered with the board;
 - (c) shall not accept employment without the prior written approval of the board: Provided that this prohibition shall not apply in the case of a full-time or part-time appointment in the health or education sectors in the public service; and
 - (d) shall not conduct a private practice.

Performance of professional acts by student in the speech, language and hearing professions

7. A student in the speech, language and hearing professions –
- (a) shall perform professional acts only under supervision of a practitioner; and
 - (b) shall limit the acts referred to in paragraph (a) to acts related to his or her education and training in the profession concerned.

ANNEXURE 12

PROFESSIONAL BOARD FOR PSYCHOLOGY

RULES OF CONDUCT PERTAINING SPECIFICALLY TO THE PROFESSION OF PSYCHOLOGY

A psychologist shall adhere to the following rules of conduct in addition to the rules of conduct referred to in rules 2 to 27. Failure by such psychologist to comply with the rules of conduct listed herein shall constitute an act or omission in respect of which the board may take disciplinary steps in terms of Chapter IV of the Act.

1. Definitions

In these rules, any word or expression to which a meaning has been assigned in the Act shall bear such meaning and, unless the context otherwise indicates - “**Act**” means the Health Professions Act, 1974(Act No.56 of 1974); “**barter**” means the acceptance of goods, services or other non- monetary remuneration from clients in return for psychological services;

“**board**” means the Professional Board for Psychology established in terms of section 15 of the Act;

“**children**” means persons 14 years and younger and the word “child” has a similar meaning;

“**client**” means a user of psychological services, irrespective of whether the recipient of such services is an individual, a family, a group, an organisation or a community;

“**competency**” means the ability to conduct the psychological acts in which a psychologist was trained and in which he obtained a qualification as prescribed in terms of the Act; “

confidential information” means any information conveyed in confidence to a psychologist by a client, colleague, collateral source or another professional;

“**health committee**” means a committee established by the council in terms of section 10(1) and the regulations made under section 51 of the Act;

“**intern**” means a person registered as an intern in psychology under the Act;

“**psychological services**” means the acts of psychological assessment, diagnosis and intervention rendered to a client;

“**psychologist**” includes a person registered under the Act as a psychologist, registered counsellor, psychometrist, psycho-technician, intern in psychology or student in professional psychology;

“**psychometrist**” means a person registered as a psychometrist in terms of the Act;

“**psycho-technician**” means a person registered as a psycho-technician in terms of the Act; “**registered counsellor**” means a person registered as a registered counsellor in terms of the Act; “**section**” means a section of the Act;

“**sexual harassment**” means any act of sexual solicitation, physical advances, or verbal or nonverbal conduct that is sexual in nature that is committed by a psychologist in the course of his or her professional activities and that is unwelcome or offensive or creates an untenable situation in the workplace or educational environment;

“**student**” means a person registered under the Act as a student in professional psychology;

“**test data**” means the test protocols, record forms, scores and notes regarding an individual’s responses to test items in any medium;

“**the code**” means these rules.



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

NATIONAL PATIENTS' RIGHTS CHARTER

BOOKLET 3

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcsa@hpcsa.co.za

Website: <http://www.hpcsa.co.za>

ETHICAL AND PROFESSIONAL RULES

Practice as a health care professional is based on a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society.

In the course of their professional work health care practitioners are required to subscribe to certain rules of conduct. To this end the Health Professional Council of South Africa has formulated a set of rules regarding professional conduct against which complaints of professional misconduct will be evaluated. These rules are reproduced in this booklet.

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

PREAMBLE.....	1
1 INTRODUCTION.....	1
2 PATIENTS' RIGHTS.....	1
3 RESPONSIBILITIES OF THE PATIENT	3

NATIONAL PATIENTS' RIGHTS CHARTER

PREAMBLE

The Department of Health, in consultation with various other bodies, developed a National Patients' Rights Charter.

The document contained herein was launched by the Minister of Health and agreed to by the HPCSA. It has since been included in the Board's *Handbook for Interns, Accredited facilities and Health Authorities*.

NATIONAL PATIENTS' RIGHTS CHARTER

1. INTRODUCTION

- 1.1 For many decades the vast majority of the South African population has experienced either a denial or violation of fundamental human rights, including rights to health care services.
- 1.2 To ensure the realisation of the right of access to health care services as guaranteed in the *Constitution of the Republic of South Africa, 1996* (Act No. 109 of 1996), the Department of Health is committed to upholding, promoting and protecting this right and, therefore, proclaims this PATIENTS' RIGHTS CHARTER as a common standard for achieving the realisation of this right.
- 1.3 Equally, Practitioners should adhere to the stipulations of this charter as it relates to them.

2. PATIENTS' RIGHTS

2.1 HEALTHY AND SAFE ENVIRONMENT

Everyone has a right to a healthy and safe environment that will ensure their physical and mental health or well-being, including adequate water supply, sanitation and waste disposal, as well as protection from all forms of environmental danger, such as pollution, ecological degradation or infection.

2.2 PARTICIPATION IN DECISION-MAKING

Every citizen has the right to participate in the development of health policies, whereas everyone has the right to participate in decision-making on matters affecting one's own health.

2.3 ACCESS TO HEALTH CARE

Everyone has the right to access to health care services that include -

- a. **receiving timely emergency care** at any health care facility that is open, regardless of one's ability to pay;
- b. **treatment and rehabilitation** that must be made known to the patient to enable the patient to understand such treatment or rehabilitation and the consequences thereof;
- c. **provision for special needs** in the case of newborn infants, children, pregnant women, the aged, disabled persons, patients in pain, persons living with HIV or AIDS patients;
- d. **counselling** without discrimination, coercion or violence on matters such as reproductive health, cancer or HIV/AIDS;
- e. **palliative care** that is affordable and effective in cases of incurable or terminal illness;
- f. a **positive disposition** displayed by health care providers that demonstrates courtesy, human dignity, patience, empathy and tolerance;
- g. **health information** that includes information on the availability of health services and how best to use such services, and such information shall be in the language understood by the patient.

2.4 KNOWLEDGE OF ONE'S HEALTH INSURANCE/MEDICAL AID SCHEME

A member of a health insurance or medical aid scheme is entitled to information about that health insurance or medical aid scheme and to challenge, where necessary, the decision of such health insurance or medical aid scheme relating to the member.

2.5 CHOICE OF HEALTH SERVICES

Everyone has a right to choose a particular health care provider for services or a particular health facility for treatment, provided that such choice shall not be contrary to the ethical standards applicable to such health care provider or facility.

2.6 TREATED BY A NAMED HEALTH CARE PROVIDER

Everyone has a right to know the person that is providing health care and, therefore, must be attended to by only clearly identified health care providers.

2.7 CONFIDENTIALITY AND PRIVACY

Information concerning one's health, including information concerning treatment may only be disclosed with informed consent, except when required in terms of any law or any order of court.

2.8 INFORMED CONSENT

Everyone has a right to be given full and accurate information about the nature of one's illnesses, diagnostic procedures, the proposed treatment and risks associated therewith and the costs involved.

2.9 REFUSAL OF TREATMENT

A person may refuse treatment and such refusal shall be verbal or in writing, provided that such refusal does not endanger the health of others.

2.10 A SECOND OPINION

Everyone has the right on request to be referred for a second opinion to a health provider of one's choice.

2.11 CONTINUITY OF CARE

No one shall be abandoned by a health care professional who or a health facility which initially took responsibility for one's health without appropriate referral or hand-over.

2.12 COMPLAINTS ABOUT HEALTH SERVICES

Everyone has the right to complain about health care services, to have such complaints investigated and to receive a full response on such investigation.

3. RESPONSIBILITIES OF THE PATIENT

Every patient or client has the following responsibilities:

- 3.1 To take care of his or her own health.
- 3.2 To care for and protect the environment.
- 3.3 To respect the rights of other patients and health care providers.
- 3.4 To utilise the health care system properly and not to abuse it.
- 3.5 To know his or her local health services and what they offer.
- 3.6 To provide health care providers with relevant and accurate information for diagnostic, treatment, rehabilitation or counselling purposes.
- 3.7 To advise health care providers of his or her wishes with regard to his or her death.
- 3.8 To comply with the prescribed treatment or rehabilitation procedures.
- 3.9 To enquire about the related costs of treatment and/or rehabilitation and to arrange for payment.
- 3.10 To take care of the health records in his or her possession.



**THE HEALTH CARE PROFESSIONS COUNCIL OF SOUTH
AFRICA**

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

**SEEKING PATIENTS' INFORMED CONSENT:
THE ETHICAL CONSIDERATIONS**

BOOKLET 4

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcsas@hpcsas.co.za

Website: <http://www.hpcsas.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practice as a health care professional is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1.	GUIDANCE TO HEALTH CARE PRACTITIONERS	3
2.	INTRODUCTION.....	3
3.	CONSENT TO INVESTIGATION AND TREATMENT	3
3.1	PROVIDING SUFFICIENT INFORMATION	3
3.2	RESPONDING TO QUESTIONS	5
3.3	WITHHOLDING INFORMATION.....	6
3.4	PRESENTING INFORMATION TO PATIENTS.....	6
4.	WHO OBTAINS CONSENT?	7
5.	THE RIGHT OF PATIENTS TO INFORMATION.....	7
6.	ENSURING VOLUNTARY DECISION MAKING	8
7	EMERGENCIES.....	8
8	ESTABLISHING CAPACITY TO MAKE DECISIONS	9
8.1	ASSESSING MENTAL CAPACITY	9
8.2	FLUCTUATING CAPACITY.....	9
8.3	MENTALLY INCAPACITATED PATIENTS	9
8.4	THIRD PARTY NOMINATIONS IN REGARD TO CONSENT	10
8.5	CHILDREN.....	10
9.	THE “BEST INTERESTS” PRINCIPLE	11
10.	APPLYING TO THE COURT	12
11.	FORMS OF CONSENT	12
12.	EXPRESS CONSENT	12
13.	STATUTORY REQUIREMENTS.....	13
14.	IMPLIED CONSENT	13
15.	REVIEWING CONSENT	13
16.	CONSENT TO SCREENING AND TESTING.....	13
18.	ICD10 CODING AND INFORMED CONSENT	14
18.1	PROVIDER RESPONSIBILITIES: ICD-10	14
18.2	INFORMED CONSENT FOR INTER-COUNCIL INTERACTION OF HEALTH PROFESSIONALS AS MEMBERS OF A HEALTH CARE TEAM.....	15

SEEKING PATIENTS' INFORMED CONSENT: THE ETHICAL CONSIDERATIONS

1. GUIDANCE TO HEALTH CARE PRACTITIONERS

Being registered under the Health Professions Act, 1976 (Act No. 56 of 1974), gives health care practitioners certain rights and privileges. In return, you must meet the standards of competence, care and conduct set by the Health Professions Council of South Africa.

This booklet sets out the principles of good practice which all health care practitioners are expected to follow when seeking patients' informed consent to investigations, treatment, screening or research.

2. INTRODUCTION

- 2.1 Successful relationships between health care practitioners and patients depend upon mutual trust. To establish that trust practitioners must respect patients' autonomy - their right to decide whether or not to undergo any medical intervention, even where a refusal may result in harm to themselves or in their own death. Patients must be given sufficient information in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. This is what is meant by an informed consent
- 2.2 The right to an informed consent flows from the South African Constitution, the National Health Act, various other statutes, the common law and the HPCSA Guidelines. Health care practitioners are expected to be aware of the law in this regard. The law prescribes the minimum requirements when seeking informed consent from patients.
- 2.3 Effective communication is the key to enabling patients to make informed decisions. Health care practitioners must take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment. Such dialogue with patients leads to clarity of objectives and understanding, and strengthens the quality of the relationship between health care practitioners and patients. It provides an agreed framework within which health care practitioners can respond effectively to the individual needs of patients. Patients who make properly informed decisions about their health care are more likely to co-operate fully with the agreed management of their conditions.

3. CONSENT TO INVESTIGATION AND TREATMENT

3.1 PROVIDING SUFFICIENT INFORMATION

- 3.1.1 Patients have a right to information about their condition and the treatment options available to them. The amount of information that must be given to each patient will vary according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes. For example, patients may need more information to make an informed decision about a procedure which carries a high risk of failure or adverse side effects, or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life.
- 3.1.2 The National Health Act requires patients to be given information about:

- 3.1.2.1 Their patient's health status except in circumstances where there is substantial evidence that the disclosure of the patient's health status would be contrary to the best interests of the patient;
 - 3.1.2.2 The range of diagnostic procedures and treatment options generally available to the patient;
 - 3.1.2.3 The benefits, risks costs and consequences generally associated with each option; and
 - 3.1.2.4 The patient's right to refuse health services and explain the implications, risks and obligations of such refusal.
- 3.1.3 Patients have a right to information about any condition or disease from which they are suffering. This information should be presented in a language that the patient understands. The information which patients want or ought to know, before deciding whether to consent to treatment or an investigation, includes:
- 3.1.3.1 Details of the diagnosis and prognosis, and the likely prognosis if the condition is left untreated;
 - 3.1.3.2 Uncertainties about the diagnosis, including options for further investigation prior to treatment;
 - 3.1.3.3 Options for treatment or management of the condition, including the option not to treat;
 - 3.1.3.4 The purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patient should prepare for the procedure; and details of what the patient might experience during or after the procedure including common and serious side effects;
 - 3.1.3.5 For each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused or necessitated by the treatment;
 - 3.1.3.6 Advice about whether a proposed treatment is experimental;
 - 3.1.3.7 How and when the patient's condition and any side effects will be monitored or re-assessed;
 - 3.1.3.8 The name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team;
 - 3.1.3.9. Whether students will be involved, and the extent to which students may be involved in an investigation or treatment;
 - 3.1.3.10 A reminder that patients can change their minds about a decision at any time;
 - 3.1.3.11 A reminder that patients have a right to seek a second opinion;
 - 3.1.3.12 Details of costs or charges which the patient may have to meet.
- 3.1.4 When providing information, health care practitioners must do their best to find out about patients' individual needs and priorities. For example, patients' beliefs, culture, occupation or other factors may have a bearing on the information they need in order to reach a

decision. Health care practitioners should not make assumptions about patients' views, but discuss these matters with them and ask them whether they have any concerns about the treatment or the risks it may involve. Health care practitioners should provide patients with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Patients should be asked whether they have understood the information and whether they would like more before making a decision.

- 3.1.5 Health care practitioners must not exceed the scope of the authority given by a patient, except in an emergency. Therefore, health care practitioners providing treatment or undertaking investigations, must give the patient a clear explanation of the scope of consent being sought. This will apply particularly where:
- 3.1.5.1 Treatment will be provided in stages with the possibility of later adjustments;
 - 3.1.5.2 Different health care practitioners provide particular elements of an investigation or treatment (for example anaesthesia during surgery);
 - 3.1.5.3 A number of different investigations or treatments are involved;
 - 3.1.5.4 Uncertainty about the diagnosis or about the appropriate range of options for treatment may be resolved only in the light of findings once an investigation or treatment is underway, and when the patient may be unable to participate in decision making.
- 3.1.6 In the cases referred to in para 3.1.5 above, health care practitioners should explain how decisions will be made about whether or when to move from one stage or one form of treatment to another. There should be a clear agreement about whether the patient consents to all or only parts of the proposed plan of investigation or treatment, and whether further consent will have to be sought at a later stage.
- 3.1.7 Health care practitioners should raise with patients the possibility of additional problems emerging during a procedure when the patient is unconscious or otherwise unable to make a decision. They should seek consent to treat any problems which they think may arise and ascertain whether there are any procedures to which the patient would object, or prefer to give further thought to before they proceed. Health care practitioners must abide by patients' decisions on these issues. If in exceptional circumstances health care practitioners decide, while the patient is unconscious, to treat a condition which falls outside the scope of the patient's consent, their decision may be challenged in the courts, or be the subject of a complaint to their employers or the HPCSA. Health care practitioners should therefore seek the views of an experienced colleague, wherever possible, before providing the treatment. They must be prepared to explain and justify their decisions based on such consideration as preservation of life. Health care practitioners must tell the patient what they have done and why, as soon as the patient is sufficiently recovered to understand.

3.2 RESPONDING TO QUESTIONS

Health care practitioners must respond honestly to any questions the patient raises and, as far as possible, answer as fully as the patient wishes. In some cases, a patient may ask about other treatments that are unproven or ineffective. Some patients may want to know whether any of the risks or benefits of treatment are affected by the choice of institution or doctor providing the care. Health care practitioners must answer such questions as fully, accurately and objectively as possible.

3.3 WITHHOLDING INFORMATION

- 3.3.1 Health care practitioners should not withhold information necessary for decision making unless they judge that disclosure of some relevant information would cause the patient serious harm. In this context, serious harm does not mean the patient would become upset or decide to refuse treatment.
- 3.3.2 The South African courts have held that patients must be informed of all “material risks” in order to give a proper informed consent. A risk is “material” if:
- 3.3.2.1 A reasonable person in the position of the patient, if warned of the risk, would attach significance to it; and
 - 3.3.2.2 The health care practitioner should reasonably be aware that the patient, if warned of the risk, would attach significance to it.
- 3.3.3 No-one may make decisions on behalf of a mentally competent adult. If patients ask health care practitioners to withhold information and make decisions on their behalf, or nominate a relative or third party to make decisions for them, the health care practitioner should explain the importance of patients knowing the options open to them, and what the treatment they may receive will involve. If patients insist they do not want to know in detail about their condition and its treatment, the health care practitioner should still provide basic information about the treatment. If a relative asks a health care practitioner to withhold information, the latter must seek the views of the patient. Again, health care practitioners should not withhold relevant information unless they judge that it would cause the patient serious harm.
- 3.3.4 The National Health Act provides that health care practitioners must provide patients (i.e. patients) with information about their health status unless “there is substantial evidence that the disclosure of the patient’s health status would be contrary to the best interests of the patients”.
- 3.3.5 In any case where health care practitioners withhold relevant information from the patient they must record this, and the reason for doing so, in the patient's medical records and they must be prepared to explain and justify their decision.

3.4 PRESENTING INFORMATION TO PATIENTS

- 3.4.1 Obtaining informed consent cannot be an isolated event. It involves a continuing dialogue between health care practitioners and their patients which keeps them abreast of changes in the condition of patients and the treatment or investigation the practitioners propose. Whenever possible, health care practitioners should discuss treatment options at a time when the patient is best able to understand and retain the information.
- 3.4.2 To be sure that their patients understand, health care practitioners should give clear explanations and give the patients time to ask questions. In particular, health care practitioners should:
- 3.4.2.1 Use up-to-date written material, visual and other aids to explain complex aspects of the investigation, diagnosis or treatment where appropriate and practicable;
 - 3.4.2.2 Make arrangements, wherever possible, to meet particular language and communication needs, for example through translations, independent interpreters, people who sign on behalf of patients, or the patient's representative;

- 3.4.2.3 Where appropriate, discuss with patients the possibility of being accompanied by a relative or friend,
- 3.4.2.4 Explain the probabilities of success, or the risk of failure of, or harm associated with options for treatment, using accurate data;
- 3.4.2.5 Ensure that information which patients may find distressing is given to them in a considerate way. Provide patients with information about counseling services and patient support groups, where appropriate;
- 3.4.2.6 Allow patients sufficient time to reflect, before and after making a decision, especially where the information is complex or the severity of the risks is great. Where patients have difficulty understanding information, or there is a lot of information to absorb, it may be appropriate to provide it in manageable amounts, with appropriate written or other back-up material, over a period of time, or to repeat it;
- 3.4.2.7 Involve nursing or other members of the health care team in discussions with the patient, where appropriate. They may have valuable knowledge of the patient's background or particular concerns, for example in identifying what risks the patient should be told about);
- 3.4.2.8 Ensure that, where treatment is not to start until sometime after consent has been obtained, patients are given clear instructions on how to review their decision with the health care practitioner providing the treatment.
- 3.4.2.9 Consent will not be informed if it was given as a result of duress, coercion, manipulation, misrepresentation or mental impairment (e.g. under the influence of alcohol, drugs, including premedication in the theatre).

4. WHO OBTAINS CONSENT?

- 4.1 A health care practitioner providing treatment or undertaking an investigation, has the responsibility to discuss it with the patient and obtain consent, as the practitioner will have a comprehensive understanding of the procedure or treatment, how it is to be carried out, and the risks attached to it. Where this is not practicable, health care practitioners may delegate these tasks provided they ensure that the person to whom they delegate:
 - 4.1.1 Is suitably educated, trained and qualified;
 - 4.1.2 Has sufficient knowledge of the proposed investigation or treatment and understands the risks involved; and
 - 4.1.3 Acts in accordance with the guidance in this Booklet.
- 4.2 A health care practitioner will remain responsible for ensuring that, before he or she starts any treatment, the patient has been given sufficient time and information to make an informed decision, and has given consent to the investigation or procedure

5. THE RIGHT OF PATIENTS TO INFORMATION

- 5.1 Patients have a right to information about the health care services available to them, presented in a way that is easy to follow and use.

- 5.2 The National Health Act provides that health care providers (this includes health care practitioners) must inform users (patients) of the following:
- 5.2.1 The user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user;
 - 5.2.2 The range of diagnostic procedures and treatment options generally available to the user;
 - 5.2.3 The benefits, risks costs and consequences generally associated with each option; and
 - 5.2.4 The user's right to refuse health services and explain the implications, risks and obligations of such refusal.

6. ENSURING VOLUNTARY DECISION MAKING

- 6.1 It is for the patient, not the health care practitioner, to determine what is in the patient's own best interests. Nonetheless, practitioners may wish to recommend a treatment or a course of action to patients, but they must not put pressure on patients to accept their advice. In discussions with patients, health care practitioners should:
- 6.1.1 Give a balanced view of the options;
 - 6.1.2 Explain the need for informed consent.
- 6.2 Health care practitioners must declare any potential conflicts of interest, for example where they or their organisation benefit financially from the use of a particular drug or treatment, or treatment at a particular institution if permitted by the HPCSA.
- 6.3 Pressure may be put on patients by employers, insurance companies or others to undergo particular tests or accept treatment. Health care practitioners should do their best to ensure that patients have considered the options and reached their own decision. Health care practitioners should take appropriate action if they believe patients are being offered inappropriate or unlawful financial or other rewards.
- 6.4 Patients who are detained by the police or immigration authorities, or are in prison, and those detained under the provisions of any mental health legislation may be particularly vulnerable. Where such patients have a right to decline treatment, health care practitioners should do their best to ensure that they know this and are able to exercise this right.

7 EMERGENCIES

- 7.1 In an emergency, where consent cannot be obtained, health care practitioners may provide medical treatment to anyone who needs it, provided the treatment is limited to what is immediately necessary to save life or avoid significant deterioration in the patient's health.
- 7.2 However, health care practitioners must respect the terms of any valid advance refusal by the patient which they know about, or which is drawn to their attention.
- 7.3 After the emergency health care practitioners should tell the patient what has been done and why, as soon as the patient is sufficiently recovered to understand.

8 ESTABLISHING CAPACITY TO MAKE DECISIONS

8.1 ASSESSING MENTAL CAPACITY

- 8.1.1 Health care practitioners must work on the presumption that every adult has the capacity to decide whether to consent to, or refuse, proposed medical intervention, unless it is shown that they cannot understand information presented in a clear way.
- 8.1.2 If a patient's choice appears irrational, or does not accord with the health care practitioner's view of what is in the patient's best interests, this is not evidence in itself that the patient lacks competence. In such circumstances it may be appropriate to review with the patient whether all reasonable steps have been taken to identify and meet their information needs.
- 8.1.3 Where health care practitioners need to assess a patient's capacity to make a decision, they should consult the guidance issued by the relevant professional bodies.
- 8.1.4 In the case of children who have legal capacity to give consent in terms of the Child Care Act (Act No.74 of 1983) or the Choice on Termination of Pregnancy Act (Act No.92 of 1996) health care practitioners should make sure that the children are sufficiently mentally mature to understand the nature and effect of the treatment or procedure to which they are consenting (see below para 8.5).

8.2 FLUCTUATING CAPACITY

- 8.2.1 Where patients have difficulty retaining information, or are only intermittently competent to make a decision health care practitioners should provide any assistance they might need to reach an informed decision.
- 8.2.2 Health care practitioners should record any decision made while the patients were competent, including the key elements of the consultation.
- 8.2.3 Health care practitioners should review any decision made whilst the patients were competent, at appropriate intervals before treatment starts, to establish that their views are consistently held and can be relied on.

8.3 MENTALLY INCAPACITATED PATIENTS

- 8.3.1 The National Health Act makes provision for certain persons to consent on behalf of mentally incompetent patients to an operation or medical treatment where such patients are unable to give the necessary consent and have not mandated - while still mentally competent- somebody else in writing to give consent on their behalf.
- 8.3.2 The Act sets out a priority list of persons who may consent in such circumstances:
- 8.3.2.1 A person authorized by the court (e.g. a curator); or
 - 8.3.2.2 In order of priority, the patient's spouse, partner, parent, grandparent, major child or brother or sister.
- 8.3.3 Health care practitioners should also consult the provisions of the Mental Health Care Act (Act No.17 of 2002) when dealing with mentally ill patients.

8.4 THIRD PARTY NOMINATIONS IN REGARD TO CONSENT

- 8.4.1 The National Health Act allows patients – while still mentally competent - to mandate another person in writing to give consent on their behalf
- 8.4.2 If health care practitioners are treating a patient who has lost the capacity to consent to or refuse treatment, for example through the onset or progress of a mental disorder or other disability, they should try to find out whether:
- 8.4.2.1 The patient has previously mandated someone else in writing to make decisions on their behalf; or
- 8.4.2.2 Have indicated preferences in an advance statement (e.g. an “advance directive” or “living will”).
- 8.4.3 Health care practitioners must respect any refusal of treatment given when the patient was competent, provided the decision in the advance statement is clearly applicable to the present circumstances, and there is no reason to believe that the patient has changed his or her mind. Where an advance statement of this kind is not available, the patient’s known wishes should be taken into account

8.5 CHILDREN

The ages as stipulated in this document are a reflection of the Children’s Act, 2005 (Act No. 38 of 2005)

- 8.5.1 Health care practitioners must assess a child's capacity to decide whether to consent to or refuse a proposed investigation or treatment before they provide it.
- 8.5.2 In general, a competent child will be able to understand the nature, purpose and possible consequences of the proposed investigation or treatment, as well as the consequences of non-treatment.
- 8.5.3 A health care practitioner’s assessment must take account of the following:
- 8.5.3.1 A person over the age of 18 years is an adult and is legally competent to decide on all forms of treatment and medical procedures (Children’s Act, 2005).
- 8.5.3.2 A child who is 12 years of age is legally competent to consent to medical treatment if the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the treatment (Children’s Act, 2005 (Act No. 38 of 2005) section 129(2)).
- 8.5.3.3 Where a child is under 12 years of age or not of sufficient maturity and does not have the necessary mental capacity his or her parent, guardian or care-giver may give consent to medical treatment (Children’s Act, 2005 section 129(4)).
- 8.5.3.4 A child who is 12 years of age is legally competent to consent to a surgical operation if the child is of sufficient maturity, has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation, and is duly assisted by his or her parent or guardian (Children’s Act, 2005 section 129(3)).

- 8.5.3.5 Where a child is under 12 years of age or not of sufficient maturity and does not have the necessary mental capacity his or her parent or guardian may give consent to a surgical procedure (Children’s Act, 2005 section 129(5)).
- 8.5.3.6 The superintendent of a hospital or the person in charge of the hospital in the absence of the superintendent may consent to the medical treatment of or a surgical operation on a child if the treatment or operation is necessary to preserve the life of the child or to save the child from serious or lasting physical injury or disability; and the need for the treatment or operation is **so** urgent that it cannot be deferred for the purpose of obtaining consent that would otherwise have been required (Children’s Act, 2005 section 129(6)).
- 8.5.3.7 The Minister of Health may consent to the medical treatment of or surgical operation on a child if the parent or guardian of the child unreasonably refuses to give consent or to assist the child in giving consent, is incapable of giving consent or of assisting the child in giving consent, cannot readily be traced, or is deceased (Children’s Act, 2005 section 129(7)).
- 8.5.3.8 The Minister may consent to the medical treatment of or surgical operation on a child if the child unreasonably refuses to give consent (Children’s Act, 2005 section 129(8)).
- 8.5.3.9 A High Court or children’s court may consent to the medical treatment of or a surgical operation on a child in all instances where another person that may give consent refuses or is unable to give such consent (Children’s Act, 2005 section 129(9)).
- 8.5.3.10 No parent, guardian or care-giver of a child may refuse to assist a child or withhold consent by reason only of religious or other beliefs, unless that parent or guardian can show that there is a medically accepted alternative choice to the medical treatment or surgical operation concerned (Children’s Act, 2005 section 129(10)).
- 8.5.3.11 A female of any age is legally competent to consent to a termination of pregnancy (Choice on Termination of Pregnancy Act, 1996 (Act No. 92 of 1996)) provided she has the necessary mental capacity to give an informed consent by understanding and appreciating the benefits, risks, social and other implications of the termination of pregnancy.

9. THE “BEST INTERESTS” PRINCIPLE
--

- 9.1 In deciding what options may be reasonably considered as being in the best interests of a patient who lacks capacity to decide, health care practitioners should take into account:
- 9.1.1 The options for investigation or treatment which are clinically indicated;
- 9.1.2 Any evidence of the patient's previously expressed preferences, including an advance statement;
- 9.1.3 Their own and the health care team's knowledge of the patient's background, such as cultural, religious or employment considerations;

- 9.1.4 Views about the patient's preferences given by a third party who may have other knowledge of the patient, for example, the patient's partner, family, carer, or a person with parental responsibility;
- 9.1.5 Which option least restricts the patient's future choices, where more than one option (including non-treatment) seems reasonable in the patient's best interests.
- 9.2 The South African Constitution provides that "a child's best interests are paramount in every matter concerning a child".

10. APPLYING TO THE COURT

- 10.1 Where a patient's capacity to consent is in doubt, or where differences of opinion about his or her best interests cannot be resolved satisfactorily, health care practitioners should consult more experienced colleagues and, where appropriate, seek legal advice on whether it is necessary to apply to the court for a ruling.
- 10.2 Health care practitioners should seek the court where a patient lacks capacity to consent to a medical intervention and the situation is contentious for example, parents withholding consent to life-saving treatment for children under the age of 12 years.
- 10.3 Where health care practitioners decide to apply to a court they should, as soon as possible, inform the patient, or his or her representative of their decision and of his or her right to be represented at the hearing.

11. FORMS OF CONSENT

To determine whether patients have given informed consent to any proposed investigation or treatment, health care practitioners must check how well the patients have understood the details and implications of what is proposed, and not simply rely on the form in which their consent has been expressed or recorded – especially where the initial consent was obtained by a third party.

12 EXPRESS CONSENT

- 12.1 Patients can indicate their informed consent either orally or in writing.
- 12.2 In some cases, the nature of the risks to which the patient might be exposed makes it important that a written record is available of the patient's consent and other wishes in relation to the proposed investigation and treatment. This helps to ensure later understanding between health care practitioner, the patient and anyone else involved in carrying out the procedure or providing care.
- 12.3 Except in an emergency, where the patient has the capacity to give consent, health care practitioners should obtain written consent in the following cases, although this list is not exhaustive:
- 12.3.1 The treatment or procedure is complex or involves significant risks and/or side effects;
- 12.3.2 Providing clinical care is not the primary purpose of the investigation or examination;

- 12.3.3 There may be significant consequences for the patient's employment, social or personal life;
- 12.3.4 The treatment is part of a research programme.
- 12.4 Health care practitioners must use the patient's case notes or the consent form to detail the key elements of the discussion with the patient, including the nature of information provided, specific requests by the patient, and details of the scope of the consent given.

13. STATUTORY REQUIREMENTS

Some statutes require particular forms of consent to be obtained for specific procedures (for example, sterilizations (Sterilization Act (Act No. 44 of 1998), terminations of pregnancy (Choice on Termination of Pregnancy Act (No.92 of 1996) and removal of organs from dead people (National Health Act, 2003. Health care practitioners need to consult the law in this regard when carrying out such procedures.

14. IMPLIED CONSENT

Health care practitioners should be careful about relying on a patient's apparent compliance with a procedure as a form of consent. Submission in itself may not necessarily indicate consent. For example, the fact that a patient lies down on an examination couch does not indicate that the patient has understood what the health care practitioner proposes to do and why. Consent must at all times be expressed and not implied.

15. REVIEWING CONSENT

- 15.1 A signed consent form is not sufficient evidence that a patient has given, or still gives, informed consent to the proposed treatment in all its aspects. Health care practitioners must review the patient's decision close to the time of treatment, and especially where:
- 16.1.1 Significant time has elapsed between when the consent was obtained and the start of treatment;
- 16.1.2 There have been material changes in the patient's condition, or in any aspects of the proposed treatment plan, which might invalidate the patient's existing consent;
- 16.1.3 New, potentially relevant information has become available, for example about the risks of the treatment or about other treatment options.

16. CONSENT TO SCREENING AND TESTING

- 16.1 Screening or testing of healthy or asymptomatic people to detect genetic predispositions or early signs of debilitating or life threatening conditions can be an important tool in providing effective care. However, the uncertainties involved in screening or testing may be great, for example the risk of false positive or false negative results. Some findings may potentially have serious medical, social or financial consequences not only for the individuals, but for their relatives. In some cases the fact of having been screened or tested may itself have serious implications.
- 16.2 Health care practitioners must ensure that anyone considering whether to consent to screening or testing can make a properly informed decision. As far as possible, practitioners

should ensure that screening or testing is not contrary to the individual's interests. Health care practitioners must pay particular attention to ensuring that the information the person wants or ought to have is identified and provided. Practitioners should be careful to explain clearly:

- 16.2.1 The purpose of the screening or test;
- 16.2.2 The likelihood of positive or negative findings and the possibility of false positive or negative results;
- 16.2.3 The uncertainties and risks attached to the screening or testing process;
- 16.2.4 Any significant medical, social or financial implications of screening or testing for the particular condition or predisposition;
- 16.2.5 Follow up plans, including the availability of counseling and support services.

17. ICD10 CODING AND INFORMED CONSENT

Informed consent is an exercise of an **informed choice** by a patient who **has the capacity** to give consent:-

- a) in instances where there are multiple options or alternatives to treatment; or
- b) in making a decision whether to withhold or disclose information or allow someone else to disclose information on their medical condition to a defined third party; or
- c) in making a decision for purposes of reimbursement by a Medical Scheme,

based on adequate information and a detailed analysis or unpacking of each of the options or alternatives as well as the legislative requirements for disclosure of such information.

This means there must be a full and frank disclosure of all the material facts to enable the patient to decide from an informed basis. With regards to ICD 10, for instance, the patient should be given information as to who will access their information, for what purpose and what would be the implications of the utilization of such information etc.

17.1 PROVIDER RESPONSIBILITIES: ICD-10

Health care providers have the following obligations, the list not being exhaustive as any other ethical obligation in handling and dealing with patient information and respecting their confidentiality will be required:-

- a) to provide information to the patients about the legislative requirement of supplying ICD-10 codes to the medical schemes for purposes of reimbursements and the inevitable consequences of the medical scheme becoming aware of the diagnosis of the patient/member;
- b) to procure patient consent to release ICD-10 coding to the medical scheme and/or (where required) to the other health professional (within the health care team);
- c) to advise the patient of their choice not to have their ICD-10 coding divulged to the medical scheme which would mean the patient has to settle the provider's account directly; and
- d) to indicate that the practitioner does not have control over the management and utilization of this information once divulged over to the medical scheme and that the

medical scheme takes responsibility for any further disclosure or utilization of such information for whatever purpose.

It is strongly suggested that written consent be procured from the patients by the providers in order to safeguard the interests of both parties. Consent by a patient may be once-off in relation to the treatment of a similar condition provided there is a verbal reminder to the patient about their initial commitment to confirm if they are still comfortable with the disclosure. It would be advisable for a provider to note the verbal reminder on that patient's file. Where a patient presents with a new or different condition, a fresh consent should be obtained from the patient and appropriately documented.

Providers without a direct patient contact like pathologists and radiologists act on referrals from other providers. Their responsibility would be to ensure that the referring provider has procured consent for that other provider (in this case a pathologist or radiologist) to access and also disclose the information to the medical scheme for reimbursement purposes.

17.2 INFORMED CONSENT FOR INTER-COUNCIL INTERACTION OF HEALTH PROFESSIONALS AS MEMBERS OF A HEALTH CARE TEAM

Sharing of information with members of a health care team providing a health service to a patient would be permissible to the extent that it is necessary to enhance the quality of care to be provided to that patient and the patient has given consent to treatment and disclosure of such information to another healthcare practitioner. This would include members beyond the HPCSA.



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE IN THE HEALTH CARE
PROFESSIONS**

**CONFIDENTIALITY: PROTECTING AND
PROVIDING INFORMATION**

BOOKLET 5

**PRETORIA
SEPTEMBER 2016**

Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcs@hpcs.co.za

Website: <http://www.hpcs.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practice as a health care professional is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1. INTRODUCTION	ERROR! BOOKMARK NOT DEFINED.
2. DEFINITIONS	1
3. PATIENTS' RIGHT TO CONFIDENTIALITY	2
4. RETAINING CONFIDENTIALITY	3
5. PROTECTING INFORMATION	3
6. THE RIGHT OF PATIENTS TO INFORMATION	3
7. DISCLOSURE OF INFORMATION TO OTHERS PROVIDING CARE	4
8. DISCLOSURE OF INFORMATION OTHER THAN FOR TREATMENT OF INDIVIDUAL PATIENTS	5
9. PUTTING THE PRINCIPLES INTO PRACTICE	6
10. DISCLOSURE IN CONNECTION WITH JUDICIAL OR OTHER STATUTORY PROCEEDINGS	11
11. ELECTRONIC PROCESSING OF INFORMATION	11

CONFIDENTIALITY: PROVIDING AND PROTECTING INFORMATION

1. PRE-AMBLE

- 1.1 Being registered under the Health Professions Act, 1974 (Act No. 56 of 1974), gives health care practitioners certain rights and privileges. In return, they have the duty to meet the standards of competence, care and conduct set by the Health Professions Council of South Africa and its Professional Boards.
- 1.2 Health care practitioners hold information about patients that is private and sensitive. The National Health Act (Act No. 61 of 2003) provides that this information must not be given to others, unless the patient consents or the health care practitioner can justify the disclosure. Practitioners are responsible for ensuring that clerks, receptionists and other staff respect confidentiality in their performance of their duties. Guidelines on when disclosures may be justified are provided in this booklet.
- 1.3 When a health care provider is satisfied that information should be released, he or she should act promptly to disclose all relevant information. This is often essential to protect the best interests of the patient, or to safeguard the well-being of others.
- 1.4 These guidelines on confidentiality are the result of extensive discussion and debate with professional and patient groups and the provisions of the National Health Act. They place new responsibilities on health care practitioners regarding the obtaining of consent for and keeping patients informed about the disclosure of information concerning them. The guidelines set out a framework for respecting patients' rights, while ensuring that information needed to maintain and improve health care for individual patients and society is disclosed to those who need it for such purposes.
- 1.5 The additional duties on health care practitioners to obtain consent and to anonymise data are consistent with the provisions of the National Health Act. These guidelines ensure privacy-friendly relationships between patients and practitioners and should assist health care practitioners to comply with their ethical and legal obligations.
- 1.6 These guidelines are based upon international ethical codes, the South African Constitution (Act No. 108 of 1996) and the National Health Act (Act No. 61 of 2003).

2. DEFINITIONS

This section defines the terms used in this document.

- 2.1 "Anonymised data" means data from which the patient cannot be identified by the recipient of the information. The name, address, and full postal code must be removed, together with any other information which, in conjunction with other data held by or disclosed to the recipient, could identify the patient. Patient reference numbers or other unique numbers may be included only if recipients of the data do not have access to the 'key' to trace the identity of the patient using that number.

- 2.2 “Consent” in terms of the National Health Act means consent for the provision of a specified health service given by a person with legal capacity. A person older than 12 years may consent to medical and surgical treatment subject to being sufficiently mature to provide the consent, (Children’s Act (Act No. 38 of 2005) and a female of any age may consent to a termination of pregnancy (Choice on Termination of Pregnancy Act (Act No. 92 of 1996)). For more information on Consent consult Booklet 9 on *Seeking patients’ informed consent: Ethical considerations*.
- 2.3 “Express consent” means consent which is expressed orally or in writing (except where patients cannot write or speak, when other forms of communication may be sufficient).
- 2.4 “Health care personnel” in terms of the National Health Act includes both health care providers and health workers (i.e. the health care team that provide clinical services for users or patients, and the administrative staff who support these services). The Act includes health care practitioners under the term “health care providers”. For the purposes of these guidelines the term “health care practitioners” refers to practitioners registered with the HPCSA.
- 2.5 “Patients” are referred to as “users” in the National Health Act. A “user” is a person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service. “User” includes persons who are authorised to give consent in terms of the National Health Act where the patient is incompetent to give consent (see Booklet 9 on *Seeking patients’ informed consent: Ethical considerations*).
- 2.6 “Personal information” means information about people that health care practitioners learn in a professional capacity and from which individuals can be identified.
- 2.7 “Public interest” mean the interests of the community as a whole, or individuals or a group within the community.

3. PATIENTS’ RIGHT TO CONFIDENTIALITY
--

- 3.1 The National Health Act (Act No. 61 of 2003) states that all patients have a right to confidentiality and this is consistent with the right to privacy in the South African Constitution (Act No. 108 of 1996).
- 3.2 Rule 13 of the Ethical Rules of the HPCSA states that a practitioner may divulge information regarding a patient only if this is done:
- 3.2.1 In terms of a Statutory provision,
 - 3.2.2 At the instruction of a court,
 - 3.2.3 In the public interest,
 - 3.2.4 With the express consent of the patient,
 - 3.2.5 With the written consent of a parent or guardian of a minor under the age of 12 years,

3.2.6 In the case of a deceased patient with the written consent of the next of kin or the executor of the deceased's estate.

3.3 Disclosures in the public interest would include but not be limited to situations where the patient or other persons would be prone to harm as a result of risk related contact.

4. RETAINING CONFIDENTIALITY

4.1 Patients have a right to expect that information about them will be held in confidence by health care practitioners. Confidentiality is central to trust between practitioners and patients. Without assurances about confidentiality, patients may be reluctant to give practitioners the information they need in order to provide good care.

4.2 Where health care practitioners are asked to provide information about patients, they should :

4.2.1 Seek the consent of patients to disclosure of information wherever possible, whether or not the patients can be identified from the disclosure; Comprehensive information must be made available to patients with regard to the potential for a breach of confidentiality with ICD10 coding.

4.2.2 Anonymise data where unidentifiable data will serve the purpose;

4.2.3 Keep disclosures to the minimum necessary.

4.3 Health care practitioners must always be prepared to justify their decisions in accordance with these guidelines.

5. PROTECTING INFORMATION

5.1 The National Health Act requires that health care providers (which includes health care practitioners) and health care establishments are responsible for personal information about their patients and must make sure that such information is effectively protected against improper disclosure at all times. For example, this means that employees such as clerks and receptionists must also be trained to respect the confidentiality of patients when dealing with personal information.

5.2 Many improper disclosures are unintentional. Health care practitioners should not discuss information about patients where they can be overheard or leave patients' records where they are vulnerable to disclosure, either on paper or electronically, where they can be seen by other patients, unauthorised health care personnel or the public. Health care practitioners should endeavour to ensure that their consultations with patients are private.

6. THE RIGHT OF PATIENTS TO INFORMATION

6.1 Patients have a right to information about the health care services available to them, presented in a way that is easy to follow and use.

6.2 The National Health Act provides that health care providers (this includes health care practitioners) must inform patients (patients) of the following:

- 6.2.1 The patient's health status except in circumstances where there is substantial evidence that the disclosure of the patient's health status would be contrary to the best interests of the patients;
 - 6.2.2 The range of diagnostic procedures and treatment options generally available to the patients;
 - 6.2.3 The benefits, risks costs and consequences generally associated with each option; and
 - 6.2.4 The patient's right to refuse health services and explain the implications, risks and obligations of such refusal.
- 6.3 Patients also have a right to information about any condition or disease from which they are suffering. Such information should be presented in a manner easy to follow and use, and should include information about the diagnosis, prognosis, treatment options, outcomes of treatment, common and serious side-effects of treatment, the likely time-frames of treatment, and the expected costs, where relevant.
- 6.4 Health care practitioners should always give patients basic information about the treatment they propose to provide, but should respect the wishes of any patient who asks not to be given detailed information. The latter requests place a considerable onus upon health care providers because, without such information, patients cannot make proper choices as partners in the health care process.

7. DISCLOSURE OF INFORMATION TO OTHERS PROVIDING CARE

- 7.1 Health care practitioners should make sure that patients are aware that personal information about them will be shared within the health care team - and patients must be told the reasons for this. It is particularly important to check that patients understand what will be disclosed if it is necessary to share personal information with anyone employed by another organisation or agency providing health or social care. Practitioners cannot treat patients safely, nor provide continuity of care, without having relevant information about the patient's condition and medical history.
- 7.2 In some circumstances where patients have consented to treatment, express consent (orally or in writing) is not usually needed before relevant personal information is shared to enable the treatment to be provided. For example, express consent is not needed before a general practitioner discloses relevant personal information to a medical secretary so that she can type a referral letter. In such circumstances, when the practitioner informs the patient that he or she is referring the patient to somebody else, the patient is assumed to have given implied consent to such disclosure being made to the secretary.
- 7.3 The health care practitioner must make sure that any recipient to whom personal information about patients is disclosed, understands that it is given to them in confidence, which they must respect. Anyone receiving personal information in order to provide care is bound by the legal duty of confidentiality - whether or not they have contractual or professional obligations to protect confidentiality.
- 7.4 Circumstances may arise where a patient cannot be informed about the sharing of information, for example because of a medical emergency. In these cases the health care practitioner should disclose the relevant information promptly to those providing the patients' care, and explain the situation to the patient after the emergency has passed.

8. DISCLOSURE OF INFORMATION OTHER THAN FOR TREATMENT OF INDIVIDUAL PATIENTS

8.1 PRINCIPLES

- 8.1.1 Information about patients is requested for a wide variety of purposes including education, research, monitoring and epidemiology, public health surveillance, clinical audit, administration and planning, insurance and employment. Health care practitioners have a duty to protect the privacy of patients and respect their autonomy. When asked to provide information health care practitioners should adhere to the principles in para 4.2 above.
- 8.1.2 The paragraphs below deal with obtaining consent for disclosure of information and what to do where consent is unobtainable, or where it is impracticable to seek consent for disclosure of information.

8.2 OBTAINING CONSENT FOR DISCLOSURE

- 8.2.1 Seeking consent of patients to disclosure is part of good communication between health care practitioners and patients and is an essential part of respect for the autonomy and privacy of patients. The following principles should be applied:
- 8.2.2 Obtaining consent where the disclosures will have personal consequences for patients:
- 8.2.2.1 Health care practitioners must obtain express consent where patients may be personally affected by the disclosure, for example when disclosing personal information to a patient's employer or to a medical scheme for ICD-10 coding.
 - 8.2.2.2 When seeking express consent, health care practitioners must make sure that patients are given enough information on which to base their decision, the reasons for the disclosure and the likely consequences of the disclosure.
 - 8.2.2.3 Health care practitioners should also explain how much information will be disclosed and to whom it will be given.
 - 8.2.2.4 If the patient withholds consent the health care practitioner should first attempt to persuade the patient to consent.
 - 8.2.2.5 If the patient continues to refuse consent, or consent cannot be obtained, the consequences of disclosure and non-disclosure should be explained to the patient. Disclosures may be made only where they can be justified in the public interest.
- 8.2.3 Obtaining consent where the disclosure is made for research, educational, training, efficient administration of health services or clinical audit purposes:
- 8.2.3.1 If identifiable data is to be used this can only be done with informed consent of the patient
 - 8.2.3.2 Use of identifiable patient data is permitted for purposes of the efficient administration of health services and for clinical audit, with the proviso that only information relevant to the purpose of disclosure is revealed, and disclosure is only made to personnel with a direct interest in that information.

8.2.3.3 Where de-identified information can serve any of the above purposes, it is incumbent on the health care provider to de-identify these data as soon as possible before making use of the data.

8.2.3.4 Where health care practitioners have control of personal information about patients, they must not allow anyone access to that information for study, research or medical audit unless the person obtaining access has been properly trained and authorised by a health establishment, a health care provider or comparable body and is subject to a duty of confidentiality in their employment or because of their registration with a statutory regulatory body.

8.2.4 Disclosures in the public interest:

8.2.4.1 In cases where health care practitioners have considered all the available means of obtaining consent, but are satisfied that it is not practicable to do so, or that patients are not competent to give consent, or exceptionally, in cases where patients withhold consent, personal information may be disclosed in the public interest where the benefits to an individual or to society of the disclosure outweigh the public and the patient's interest in keeping the information confidential, (e.g. endangered third parties such as the spouse or partner of a patient who is HIV positive, who after counselling refuses to disclose his or her status to such spouse or partner; or reporting a notifiable disease).

8.2.4.2 In all such cases the health care practitioner must weigh the possible harm (both to the patient, and the overall trust between practitioners and patients) against the benefits that are likely to arise from the release of information.

8.2.4.3 Examples of circumstances to protect the patient or other persons from death or serious harm, include, but are not limited to:

- a. Access to prophylactic treatment for a person who has had contact with an infectious disease, or
- b. An employee with a health condition which may render him or her unable to work safely posing a danger to co-workers or clients
- c. A driver of a vehicle who requires medication to control an illness that might impair his or her driving ability.

9. PUTTING THE PRINCIPLES INTO PRACTICE

The remainder of this booklet deals with circumstances in which health care practitioners are most frequently asked to disclose information, and provides advice on how the principles should be applied.

9.1 DISCLOSURES WHICH BENEFIT PATIENTS INDIRECTLY

9.1.1 Monitoring public health and the safety of medicines and devices:

9.1.1.1 Professional organisations and Government regulatory bodies that monitor the public health or the safety of medicines or devices, as well as registries of notifiable conditions, rely on information from patients' records for their effectiveness in safeguarding public health. For example, the effectiveness of the system of notifiable conditions depends on information provided by clinicians. Health care practitioners must co-operate by providing relevant information

wherever possible. The notification of some communicable diseases is required by law and in other cases health care practitioners should provide information in anonymised form, when that would be sufficient.

- 9.1.1.2 Where personal information is needed, health care practitioners should seek express consent before disclosing information, whenever that is practicable. For example, where patients are receiving treatment there will usually be an opportunity for a health care practitioner to discuss disclosure of information with them.
- 9.1.1.3 Personal information may sometimes be sought about patients with whom health care practitioners are not in regular contact. Practitioners should therefore make sure that patients are given information about the possible value of their data in protecting public health in the longer-term, at the initial consultation or at another suitable occasion when they attend a health establishment.. It should be clear that they may object to disclosures at any point. The health care practitioner must record any objections so that patients' wishes can be respected. In such cases, the practitioner may pass on anonymised information if asked to do so.
- 9.1.1.4 Where patients have not expressed an objection, health care practitioners should assess the likely benefit of the disclosure to the public and commitment to confidentiality of the organisation requesting the information. If there is little or no evident public benefit, they should not disclose information without the express consent of the patient.
- 9.1.1.5 Where it is not practicable to seek the consent of patients for disclosure of personal information for these purposes, or where patients are not competent to give consent, health care practitioners must consider whether the disclosures would be justified in the public interest, by weighing the benefits to public health of the disclosure against the possible detriment to the patient.
- 9.1.1.6 The automatic transfer of personal information to a registry, whether by electronic or other means, before informing the patient that information will be passed on, is unacceptable, save in the most exceptional circumstances. These would be where a court has already decided that there is such an overwhelming public interest in the disclosure of information to a registry that rights of patients to confidentiality are overridden; or where health care practitioners are willing and able to justify the disclosure, potentially before a court or to the HPCSA, on the same grounds.

9.1.2 Administration and financial audit:

- 9.1.2.1 Health care practitioners should record financial or other administrative data separately from clinical information and provide it in anonymised form wherever possible.
- 9.1.2.2 Decisions about the disclosure of clinical records for administrative or financial audit purposes, for example where medical scheme staff seek access to patients' records as part of the arrangements for medical benefit payments, are unlikely to breach the ethical rules of the HPCSA, provided that, before allowing access to patients' records, they follow the guidelines as set out in this booklet.. Only the relevant part of the record should be made available for scrutiny.

9.1.3 Medical research:

Where research projects depend upon using identifiable information or samples, and it is not practicable to contact patients to seek their consent, the data should be anonymised and this should be drawn to the attention of a research ethics committee.

9.1.4 Publication of case-histories and photographs:

Health care practitioners must obtain express consent from patients before publishing personal information about them in media to which the public has access, for example in journals or text books, whether or not the practitioners believe the patients can be identified. Express consent must, therefore, be sought to the publication of, for example case-histories about or photographs of patients. Where health care practitioners wish to publish information about a patient who has died, they should take into account the guidelines in this booklet before deciding whether or not to do so.

9.2 DISCLOSURES WHERE HEALTH CARE PRACTITIONERS HAVE DUAL RESPONSIBILITIES

9.2.1 Situations arise where health care practitioners have contractual obligations to third parties, such as companies or organisations, as well as obligations to patients. Such situations occur, for example when practitioners:

9.2.1.1 Provide occupational health services or medical care for employees of a company or organisation;

9.2.1.2 Are employed by an organisation such as an insurance company;

9.2.1.3 Work for an agency assessing claims for benefits;

9.2.1.4 Provide medical care to patients and are subsequently asked to provide medical reports or information for third parties about them;

9.2.1.5 Work as district medical officers or forensic pathologists;

9.2.1.6 Work in the armed forces; or

9.2.1.7 Work in correctional services.

9.2.2 If health care practitioners are asked to write a report about or examine a patient, or to disclose information about a patient from existing records for a third party to whom the practitioners have contractual obligations, they must:

9.2.2.1 Be satisfied that the patient has been told at the earliest opportunity about the purpose of the examination or disclosure; the extent of the information to be disclosed; and the fact that relevant information cannot be concealed or withheld. Health care practitioners should show the form to the patient before they complete it to ensure that the patient understands the scope of the information requested;

- 9.2.2.2 Obtain, or have seen, written consent to the disclosure from the patient or a person properly authorised to act on the patient's behalf.
 - 9.2.2.3 Disclose only information relevant to the request for disclosure.
 - 9.2.2.4 Include only factual information that they can substantiate, and ensure that it is presented in an unbiased manner;
 - 9.2.2.5 Patients may wish to see reports written about them before they are disclosed, In all circumstances health care practitioners should check whether patients wish to see their reports - unless patients have clearly and specifically stated that they do not wish to do so.
- 9.2.3 Disclosures without patients' consent to employers, or any other relevant third party, can be justified only in exceptional circumstances, for example when they are necessary to protect others from risk of death or serious harm.

9.3	DISCLOSURES TO PROTECT THE PATIENT OR OTHERS
-----	--

- 9.3.1 Disclosure of personal information without consent may be justified where failure to do so may expose the patient or others to risk or death or serious harm. Where third parties are exposed to a risk so serious that it outweighs the patient's right to confidentiality, health care practitioners should seek consent to disclosure where practicable. If it is not practicable, they should disclose information promptly to an appropriate person or authority. They should generally inform the patient before disclosing the information.
- 9.3.2 Such circumstances may arise, for example:
- 9.3.1.1 A colleague who is placing patients at risk as a result of illness or some other medical condition (eg. an impaired colleague): If health care practitioners are in doubt about whether such disclosure is justified they should consult an experienced colleague, or seek advice from a professional organisation. The safety of patients must come first at all times;
 - 9.3.1.2 A patient who continues to drive, against medical advice, when unfit to do so: In such circumstances health care practitioners should consider disclosing the relevant information to the patient's next-of-kin or the traffic authorities or police. Where such a patient is employed as a professional driver the employer should be informed.
 - 9.3.1.3 A disclosure that may assist in the prevention or detection of a serious crime: In this context serious crimes, means crimes that will put someone at risk of death or serious harm, and will usually be crimes against the person, such as abuse of children.

9.4	CHILDREN AND OTHER PATIENTS WHO MAY LACK COMPETENCE TO GIVE CONSENT
-----	---

- 9.4.1 Problems may arise if health care practitioners consider that a patient is incapable of giving consent to treatment or disclosure because of immaturity, illness or mental incapacity. If such patients ask them not to disclose information to a third party, the health care practitioners should try to persuade them to allow an appropriate person to be involved in the consultation.
- 9.4.1.1 If patients refuse to give consent and health care practitioners are convinced that it is essential, in the patients' medical interests, they may disclose relevant

information to an appropriate person or authority. In such cases the health care practitioner must tell the patient before disclosing any information, and seek the consent of the person legally designated to give such consent in terms of the National Health Act.

9.4.1.2 The National Health Act provides that if no person has been mandated or legally appointed to give consent, then in the following order of precedence, a spouse or partner, parent, grandparent, adult child or adult brother or sister may give consent.

9.4.1.3 Health care practitioners should document in the patient's record the steps they took to obtain consent and the reasons for deciding to disclose information.

9.4.2 If health care practitioners believe a child or other legally incompetent patient to be a victim of neglect or physical, sexual or emotional abuse and that the patient cannot give or withhold consent to disclosure, they should give information promptly to an appropriate responsible person or statutory agency, where they believe that the disclosure is in the patient's best interests.

9.4.2.1 Health care practitioners should inform the patient that they intend to disclose the information before doing so. Such circumstances may arise in relation to children. Where child abuse is suspected the law requires the health care provider to report the alleged abuse to the relevant authorities.

9.4.2.2 Where appropriate, health care practitioners should inform those with parental responsibility about the disclosure. If, for any reason, practitioners believe that disclosure of information to the parents or guardians is not in the best interests of an abused or neglected patient, they must be prepared to justify their decision (e.g. where the parents or guardians are suspected of abusing the child).

9.4.2.3 The ages are as stipulated in this document are a reflection of the Children's Act, 2005 (Act No. 38 of 2005).

For detailed information consult the HPCSA Ethical Booklet 4 on Seeking patients' informed consent: The ethical considerations

9.5	DISCLOSURE AFTER A PATIENT'S DEATH
-----	------------------------------------

9.5.1 Health care practitioners still have an obligation to keep personal information confidential after a patient dies. The extent to which confidential information may be disclosed after a patient's death will depend upon the circumstances. These include the nature of the information, whether that information is already public knowledge or can be anonymised, and the intended use to which the information will be put. Health care practitioners should also consider whether the disclosure of information may cause distress to, or be of benefit to, the patient's partner or family.

9.5.2 There are a number of circumstances in which health care practitioners may be asked to disclose, or wish to use, information about patients who have died:

9.5.2.1 To assist in connection with an inquest. In these circumstances, practitioners are required to provide the relevant information;

9.5.2.2 As part of a clinical audit or for education or research with the approval of a research ethics committee. The publication of properly anonymised case studies would not be improper in these contexts;

- 9.5.2.3 On death certificates. The law requires health care practitioners to complete death certificates honestly and fully;
- 9.5.2.4 To obtain information relating to public health surveillance that is approved by a research ethics committee. Anonymised information should be used, unless identifiable data is essential to the study.
- 9.5.3 Particular difficulties may arise when there is a conflict of interest between parties affected by the patient's death. For example, if an insurance company seeks information in order to decide whether to make a payment under a life assurance policy, health care practitioners should only release information with consent from the next-of-kin or the executor of the deceased's estate, or if the deceased had consented to such release before his or her death.

10. DISCLOSURE IN CONNECTION WITH JUDICIAL OR OTHER STATUTORY PROCEEDINGS
--

- 10.1 Health care practitioners may be required to disclose information to satisfy a specific statutory requirement, such as notification of a notifiable disease or suspected child or elder abuse.
- 10.2 Health care practitioners must also disclose information if ordered to do so by a judge or presiding officer of a court. They should object to the judge or the presiding officer if attempts are made to compel them to disclose what appear to them to be irrelevant matters, for example matters relating to relatives or partners of the patient, who are not parties to the proceedings.
- 10.3 Health care practitioners should not disclose personal information to a third party such as a lawyer, police officer or officer of a court without the patient's express consent, except in the circumstances described in paras 9.3, 9.4.2 and 9.5.2.
- 10.4 Health care practitioners may disclose personal information in response to an official request from a statutory regulatory body for any of the health care professions, where that body determines that this is necessary in the interests of justice and for the safety of other patients. Wherever practicable they should discuss this with the patient. There may be exceptional cases where, even though the patient objects, disclosure is justified.
- 10.5 In all cases, should health care practitioners decide to disclose confidential information they must be prepared to explain and justify their decisions.

11. ELECTRONIC PROCESSING OF INFORMATION

- 11.1 Health care practitioners must be satisfied that there are appropriate arrangements for the security of personal information when it is stored, sent or received by fax, computer, e-mail or other electronic means.
- 11.2 If necessary, health care practitioners should take appropriate authoritative professional advice on how to keep information secure before connecting to a network. They should record the fact that they have taken such advice.
- 11.3 Health care practitioners must make sure that their own fax machine and computer terminals are in secure areas. If they send data by fax, they should satisfy themselves, as far as is practicable, that the data cannot be intercepted or seen by anyone other than the intended recipient.

11.4.1 When deciding whether and in what form to transmit personal information, health care practitioners should note that information sent by e-mail through the internet may be intercepted.

For detailed information consult the HPCSA Ethical Booklet 10 on Telemedicine.



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

GUIDELINES FOR GOOD PRACTICE IN THE HEALTH CARE PROFESSIONS

ETHICAL GUIDELINES FOR GOOD PRACTICE WITH REGARD TO HIV

BOOKLET 6

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcsa@hpcsa.co.za

Website: <http://www.hpcsa.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practice as a health care professional is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1	PREAMBLE.....	1
2.	HIV INFECTION AND AIDS.....	1
3	MODES OF TRANSMISSION OF HIV.....	2
4	RESPONSIBILITIES OF HEALTH CARE PRACTITIONERS TO HIV POSITIVE PATIENTS	2
5	CONFIDENTIALITY	3
6	HIV TESTING	3
7.	KNOWLEDGE OF THE HIV STATUS OF PATIENTS IN THE HEALTH CARE ENVIRONMENT	4
8.	REFUSAL TO HAVE BLOOD TESTED FOR HIV ANTIBODIES	4
9.	PARTNER DISCLOSURE.....	5
10	OCCUPATIONAL TRANSMISSION OF HIV, COMPENSATION AND INSURANCE	6
11.	HEALTH CARE PRACTITIONER'S INFECTED WITH HIV	7

GUIDELINES FOR THE MANAGEMENT OF PATIENTS WITH HIV INFECTION OR AIDS

1 PREAMBLE

- 1.1 While the guidelines focus on HIV and AIDS, many of the concerns reflected are applicable to other communicable diseases and other health issues that carry similar burdens of stigma and discrimination. However, given the enormity of the HIV and AIDS epidemic and the specific social, economic and ethical conundrums associated with HIV, these guidelines concentrate on assisting South African health care practitioners to deal with the problems associated with HIV and AIDS. This was the last paragraph
- 1.1 The HIV/AIDS epidemic has emerged as the most challenging health matter of modern times, causing intense debate and discussion in the fields of medicine, ethics, law, sociology, politics and economics. More so than any other disease in the history of humankind, HIV and AIDS have forced society and health care practitioners to re-consider important values relating to human rights, stigma, discrimination and public health.
- 1.2 South Africa has one of the most rapidly progressing HIV epidemics in the world. The HIV epidemic is undoubtedly increasing the huge burden of disease facing our country and poses a major challenge to our health and social services and to the economy of the country.
- 1.3 As health care providers committed to maximising human health and well-being, we should do all in our power to promote the prevention of HIV as well as providing access to the best possible preventive, promotional, curative and rehabilitative care.
- 1.4 These guidelines are the product of consultations with stakeholders and the revisions are consistent with international best practice, such as is contained in guidelines from the United Nations Joint Programme on HIV/AIDS (UNAIDS), the World Health Organisation (WHO) and the Department of Health (DoH) comprehensive document on HIV and AIDS.

2. HIV INFECTION AND AIDS

- 2.1.1 The human immuno virus is responsible for the epidemic facing South Africa and many other countries. For the most part initial infection with the virus in the main, is a non-event. The majority of people infected with the virus only become aware of their status by voluntarily choosing to have a HIV test. Otherwise they remain totally unaware of their HIV infection until presenting several years later with a disease associated with AIDS.
- 2.1.2 Presently there is no cure for HIV but understanding the impact of the virus on the human body has made it possible to develop effective management programmes that provides great hope for people living with HIV and AIDS. This has made HIV and AIDS a medically manageable condition – a far cry from a few years ago when despondency and depression prevailed amongst HIV positive people and their carers.

3 MODES OF TRANSMISSION OF HIV

- 3.1 HIV is transmitted primarily in three ways:
- 3.1.1 Through unprotected heterosexual or homosexual intercourse;
 - 3.1.2 During pregnancy or at birth from the infected pregnant woman to the foetus or infant; and
 - 3.1.3 Through infected blood (e.g. in drug addicts who share needles, occupational needle stick injuries or exposure to infected blood and blood transfusions).
- 3.2 The modes of transmission referred to in para 3.1 above may be effectively prevented, and health care practitioners can play an important role in this regard.
- 3.3 Much has been said of 'high risk groups or individuals' but given the complexities associated with the modes of transmission, human relationships and sexuality generalisation around the issue should not be encouraged.

4 RESPONSIBILITIES OF HEALTH CARE PRACTITIONERS TO HIV POSITIVE PATIENTS

- 4.1 The primary responsibility of health care practitioners is to their patients.
- 4.2 It is against all ethical and professional rules for a health care practitioner to refuse to treat a patient solely on the grounds of the latter's perceived or actual HIV status. Treatment should never be suboptimal because of a perceived potential HIV risk to the health care practitioner. Unilateral decisions not to resuscitate patients with HIV are violations of fundamental rights.
- 4.3 It is ethically and legally mandatory, to get informed consent before a health care practitioner tests a patient for HIV – by law this always applies except in a medical emergency, or in the case of a child where a parent or guardian is required to give consent.
- 4.4 The diagnosis of HIV, without further examination and investigation provides only the most basic information about a person's prognosis or actual state of health. It is imperative that the health care practitioner continues counselling and conducts further investigations once a patient has been diagnosed as HIV positive.
- 4.5 In the management of an HIV positive patient it is important that the health care practitioner gives due consideration to other health care professionals who are also involved in the management of the same patient (e.g. where necessary, and with the patient's consent, informing them of the HIV status of the patient).
- 4.6 Health care practitioners must support all measures aimed at preventing HIV infection. Such measures include appropriate education regarding HIV infection; alteration of lifestyle; improved management of predisposing and aggravating factors (including other sexually transmitted diseases); mobilising support from the community; and disseminating information regarding preventive measures.

5 CONFIDENTIALITY

- 5.1 Ethics, the South African Constitution (Act 108 of 1996) and the law recognise the importance of maintaining the confidentiality of the HIV status of a patient.
- 5.2 The test results of HIV positive patients should be treated with the highest possible level of confidentiality.
- 5.3 Confidentiality regarding a patient's HIV status extends to other health care practitioners. Other health care professionals may not be informed of a patient's HIV status without that patient's consent unless the disclosure is clinically indicated. For treatment and care to be in the best interests of the patient, the need for disclosure of clinical data, (including HIV and related test results), to health care practitioners directly involved in the care of the patient, should be discussed with the patient.
- 5.4 The decision to divulge information relating to the HIV status of a patient must always be done in consultation with the patient
- 5.5 The report of HIV test results by a laboratory, as is the case with all laboratory test results, should be considered confidential information. A breach of confidentiality is more likely to occur in the ward, hospital or health care practitioner's reception area than in the laboratory. It is, therefore, essential that health care institutions, pathologists and health care practitioners formulate a clear policy as to how such laboratory results will be communicated and how confidentiality of the results will be maintained.

6 HIV TESTING

- 6.1 HIV testing must only take place with the voluntary, informed consent of the patient. The South African Constitution (Act 108 of 1996) and the law recognises that testing for HIV is unlike testing for any other medical condition and that special conditions apply.
- 6.2 The attention of health care practitioners is drawn to the potential abuse of HIV test kits that are currently available on the market. Health care professionals must be aware of the reliability and safety of such kits in order to provide the necessary counselling and information to patients. New forms of HIV testing must only be adopted if they meet acceptable scientific standards.
- 6.3 In order to obtain an informed consent, the patient should be given information regarding the purpose of the laboratory test; what advantages or disadvantages testing may hold for him or her as a patient; why the health care practitioner wants this information; what influence the result of such a test will have on his or her treatment; and how his or her medical protocol will be altered by this information. The psychosocial impact of a positive test result should also be addressed.
- 6.4 All communications between the health care practitioner and the patient concerning HIV testing should be conducted in a language that is easily understood by the patient.
- 6.5 The patient must clearly understand the information provided, so that he or she agrees to the HIV test, based on a proper understanding. The importance of the patient's ability to understand the information means that if posters are displayed in an attempt to inform patients about HIV testing, these must be supplemented by verbal pre-test counselling of

the patient by the health care practitioner in order to obtain an informed consent.

- 6.6 A requirement of informed consent in respect of HIV testing is that if the patient is found to be HIV-positive, post-test counselling will follow. The health care provider must, therefore, ensure that the patient is directed to appropriate facilities that will oversee his or her further care and, where relevant, counsel his or her family and sexual partners.

7. KNOWLEDGE OF THE HIV STATUS OF PATIENTS IN THE HEALTH CARE ENVIRONMENT

- 7.1 Health care practitioners should be aware that there are factors that make it unrealistic to rely solely on HIV testing either in everyday practise or when dealing with a person who has been occupationally exposed.
- 7.2 Health care practitioners must appreciate the significance of the window period of infectivity; the prevalence of HIV infection in the community (and therefore in their patients); the different tests available; and, where applicable, the time frames necessary to obtain a reliable HIV test result.
- 7.3 There is no evidence that knowledge of the HIV status of patients protects health care practitioners or reduces the risk of needle stick injuries. However, given the high incidence of HIV infection, in all instances health care establishments should ensure that universal precautions are used to provide protection against HIV infection.
- 7.4 Where certain well-defined high risk or exposure-prone procedures are contemplated, the patient should be informed of the concerns and asked to consent to HIV testing. All patients have a right to refuse testing, and where a patient refuses to test for HIV under such circumstances, the patient may not be refused treatment on this basis. Should a patient decline to be tested for HIV, such patient should be managed by health care practitioners as if he or she was HIV positive.
- 7.5 “High risk” procedures may require the use of “extended” universal precautions such as special gloves, clothing and face masks. “High risk” procedures include, for example, the palpation of a needle-tip in a body cavity; the simultaneous presence of the health care practitioner’s fingers and a needle or other sharp object in a poorly visualised or highly confined anatomic cavity; and orthopaedic and other procedures where there is an aerosol of blood, bone fragments or bloody fluids.
- 7.6 It should be emphasised that permitting pre-operative or pre-treatment HIV testing with informed consent where high-risk procedures are contemplated, or under specific circumstances, should not be misinterpreted or abused to justify routine HIV testing of all patients, nor is it permissible for patients to be told that pre-HIV testing is mandatory in such circumstances.

8. REFUSAL TO HAVE BLOOD TESTED FOR HIV ANTIBODIES

- 8.1 It is not justifiable to test for HIV without the patient's consent, except in the circumstances set out in the National Policy on Testing for HIV, (e.g. as part of unlinked and anonymous testing for epidemiological purposes undertaken by the national, or a provincial or local health authority, or an agency authorised by any of these bodies - provided that HIV testing for epidemiological purposes is carried out in accordance with national, legal and ethical provisions regarding such testing.

- 8.2 Where the health care practitioner has sustained a risk-bearing incident such as a needle stick injury because immediate post-exposure measures may be beneficial to the health care professional, information as to the HIV status of the source patient may be obtained in the following ways:
- 8.2.1 Testing any existing blood specimen from the source patient. This should be done with the source patient's consent, but if consent is withheld, the specimen may nevertheless be tested, but only after informing the source patient that the test will be performed and providing for the protection of privacy.
 - 8.2.2 If there is no existing blood specimen and the patient still refuses to consent to an HIV test the patient should be treated as HIV positive and prophylaxis should be initiated in respect of the health care practitioner who has been placed at risk of HIV infection.
 - 8.2.3 If the patient is unable to give informed consent and is likely to remain unable to do so for a significant length of time every reasonable attempt should be made to obtain appropriate proxy consent. Proxy consent means consent by a person legally able to give such consent in terms of the National Health Act (Act No. 61 of 2003) – i.e. in order of precedence, a spouse or partner, a parent, a grandparent, an adult child or a brother or sister of the patient, or in terms of the Children's Act (Act No. 38 of 2005) the clinical manager in the absence of such persons in the case of a child.
- 8.3 It must be emphasised that with regard to HIV testing there should be no medical emergency situation and it may be difficult legally to justify such a situation on the basis that testing without consent was necessary in order to save a person's life.

9. PARTNER DISCLOSURE

- 9.1 Health care practitioners should try to encourage their HIV positive patients to disclose their status to their sexual partners so as to encourage them to undergo VCT and access treatment if necessary. This is consistent with good clinical practice.
- 9.2 If the patient refuses consent, the health care practitioner should use his or her discretion when deciding whether or not to divulge the information to the patient's sexual partner, taking into account the possible risk of HIV infection to the sexual partner and the risks to the patient (e.g. through violence) that may follow such disclosure. The decision must be made with great care, and consideration must be given to the rights of all the parties concerned. If the health care practitioner decides to make the disclosure against the patient's wishes, the practitioner must do so after explaining the situation to the patient and accepting full responsibility at all times. The following steps are recommended – the health care practitioner must:
 - 9.2.1 Counsel the patient on the importance of disclosing to his or her sexual partner and on taking other measures to prevent HIV transmission.
 - 9.2.2 Provide support to the patient to make the disclosure.
 - 9.2.3 If the patient still refuses to disclose his or her HIV status or refuses to consider other measures to prevent infection, counsel the patient on the health care practitioner's ethical obligation to disclose such information.
 - 9.2.4 If the patient still refuses, disclose information on the patient's HIV status to the sexual partner and assist them to undergo VCT and access treatment if necessary.

- 9.2.5 After disclosure, follow up with the patient and the patient's partner to see if disclosure has resulted in adverse consequences or violence for the patient, and, if so, intervene to assist the patient appropriately.
- 9.3 Health care practitioners must recognise the major ethical dilemma when confronted with a person who is HIV positive and who refuses, despite counselling, to inform his/her partner or partners.
- 9.4 When health care practitioners are expected to record diagnostic information for patients on medical insurance for the purposes of processing claims, or in line with the rules of the medical scheme, the patient must give informed consent for such information to be placed on the account (e.g. ICD-codes).

10	OCCUPATIONAL TRANSMISSION OF HIV, COMPENSATION AND INSURANCE
-----------	---

- 10.1 There is a slight risk of transmission of HIV infection in the health care environment (e.g. from patient- to-patient, patient-to-health care practitioner, and from health care practitioner-to-patient) through the exchange of infected blood or other body fluids – although scientifically the risk has been shown to be small. The risk can be reduced to negligible levels by effective infection control and hygiene measures. Nonetheless health care practitioners need to remain vigilant regarding the risk of occupational exposure to HIV.
- 10.2 Universal precautions must be practised at all times by all health care practitioners and health institutions in the health care environment.
- 10.3 Post-exposure treatment of a health care practitioner or a patient must be available where the possibility of an exchange of blood or body fluids has taken place. There can be no excuse for any health institution and practise not to have a clear and concise policy on such treatment.
- 10.4 Health practitioners working in the health care industry must make their employers aware of the importance of HIV. They should assist in the development and formulation of a comprehensive HIV and AIDS policy that covers prevention, treatment and care, as well as non-discrimination and non-stigmatisation. In developing a policy it should not be forgotten that a number of health care practitioners are themselves infected with HIV – the ethos of a caring profession should apply to fellow health care professionals. It is also imperative for employers in the health care industry to familiarise themselves with their constitutional, legal and ethical obligations when dealing with HIV and AIDS.
- 10.5 Students in faculties of health sciences, who are not legally recognised employees, and who face the possibility of occupational HIV exposure should be insured - either by their University or by the hospital where they are undergoing training.
- 10.6 There is consensus that adherence to universal precautions is the most important preventative action that will significantly protect health care practitioners against infection by HIV and other blood borne pathogens.
- 10.7 For the above reasons the following must be in place:
- 10.7.1 All employers must make available to health care practitioners the tools and systems necessary for the latter to practise universal precautions.
- 10.7.2. The necessary universal precaution tools and systems must also be provided to paramedical personnel, auxiliary and unskilled workers who handle patients (or

could be exposed to contaminated materials), and health science students who may be potentially exposed to the risk of HIV infection.

11. HEALTH CARE PRACTITIONER'S INFECTED WITH HIV

- 11.1 Health care practitioners cannot be obliged to disclose their HIV status to an employer nor may any health care practitioner be unfairly discriminated against or dismissed as a result of his or her HIV status.
- 11.2 Health care practitioners are expected to be aware of the benefits of voluntary HIV testing and are encouraged to consider VCT. Where the health care practitioner tests positive for HIV, they should attend further counselling.
- 11.3 Restrictions that cannot be scientifically justified, should not be imposed on HIV positive health care practitioners.
- 11.4 Universal precautions should always be used when undertaking invasive procedures in order to minimise transmission from health practitioners to patients.
- 11.5 Patients should be made aware by health care practitioners that HIV infection can affect everybody including health care practitioners.

ANNEXURE

1. BASIC ELEMENTS OF PRACTICALLY APPLICABLE AND UNIVERSAL PRECAUTIONS

- 1.1 Universal precautions are designed to prevent:
- 1.1.1 Penetration of the skin by contaminated sharp objects; and
 - 1.1.2 Contamination of the skin, especially non-intact skin and mucous membranes, in particular the conjunctivae.
- 1.2 As a general principle, disposable instruments should only be used once, and re-usable items should be sterilised.

2. BODY FLUIDS WHICH SHOULD BE HANDLED WITH THE SAME PRECAUTIONS AS BLOOD

- 2.1 The following body fluids should be handled with the same precautions as blood:
- 2.1.1 Cerebrospinal fluid
 - 2.1.2 Peritoneal fluid
 - 2.1.3 Pleural fluid
 - 2.1.4 Pericardial fluid
 - 2.1.5 Synovial fluid
 - 2.1.6 Amniotic fluid
 - 2.1.7 Semen
 - 2.1.8 Vaginal secretions
 - 2.1.9 Breast milk
- 2.2. The following other body fluids and tissues should also be treated like blood:
- 2.2.1 Any other body fluid which is blood stained.
 - 2.2.2 Saliva in association with dentistry.
 - 2.2.3 Unfixed tissues and organs.

3. BODY FLUIDS SUCH AS URINE, SWEAT AND SALIVA

Body fluids such as urine, sweat and saliva do not pose any risk.

4. AVOIDANCE OF INJURIES WITH "SHARPS"

Health care practitioners should avoid injuries with "sharps" by:

- 4.1 Recognising risky objects, not only needles and knives, but less obvious ones such as towel-clips, suction drain introducers, bone spicules, etc.
- 4.2 Never allowing a sharp object, especially a contaminated one, to come near one's fingers (e.g. they should not resheath needles and should use instruments to load and unload scalpel blades, etc.)
- 4.3 Being personally responsible for the immediate safe disposal of all "sharps" that they use into an approved container.
- 4.4 Never handling a "sharp" without looking at it.

- 4.5 Never putting down a "sharp" except in an agreed neutral area.
- 4.6 Using the safest "sharp" that will do the job (e.g. knives and sharp needles only for skin; scissors and blunt (round-nosed) needles for tissues).
- 4.7 Never feeling for a needle point (or other sharp object) with their fingers.
- 4.8 Never putting their fingers in an area or wound where someone else is using a "sharp".
- 4.9 Avoiding the use of wire sutures.
- 4.10 Using heavy-duty gloves (ring-link or similar) in dangerous situations (e.g. where there are broken bones, sharp foreign bodies).

5.	AVOIDANCE OF SKIN and MUCOUS MEMBRANE CONTAMINATION
----	--

- 5.1 Three risks have been identified regarding skin and mucous membrane contamination, namely from:
 - 5.1.1 Blood or body fluid on the hands;
 - 5.1.2 Spillage of blood or body fluid on the health care practitioner's body;
 - 5.1.3 Spray-aerosol of blood or body fluid to eyes and face.
- 5.2 Health care practitioners should never have contact with patients' soiled linen, etc. if the skin of their hands is not intact (e.g. from cuts, eczema, etc.) unless the lesions can be completely isolated by impermeable adhesive tape.
- 5.3 Health care practitioners should use make careful use of gloves:
 - 5.3.1 Latex gloves should be used by every health care provider handling blood or body fluid.
 - 5.3.2 Torn gloves should be removed immediately and contamination washed away.
 - 5.3.3 Double gloving reduces skin contamination during operations by 80%, and may reduce the risk associated with "sharps" injuries.
- 5.4. In respect of spillage health care practitioners should:
 - 5.4.1 Use plastic aprons and impermeable boots where the risk of spillage exists,
 - 5.4.2 Ensure that all spillage is immediately cleaned.
 - 5.4.3 Double seal all containers of blood and body fluid.
- 5.5 In respect of spray-aerosol health care practitioners should:
 - 5.5.1 Use face or eye protection (e.g. face shields, eye-goggles) where the risk of spray-aerosol contamination exists.
 - 5.5.1 Should continuously aspirate laser and fulguration smoke by suction.

Note: Routine implementation of these simple, logical measures, that are not time consuming, nor significantly expensive, by all members of the health care team, should reduce the risk of infection of health care practitioners by patients, and of patients by health care practitioners to very nearly zero. Disciplined implementation of these precautions in dealing with all patients should make pre-treatment determination of a patient's HIV status irrelevant in terms of the safety of health care practitioners.



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR THE WITHHOLDING AND
WITHDRAWING OF TREATMENT**

BOOKLET 7

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcsa@hpcsa.co.za

Website: <http://www.hpcsa.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".^[1] To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, the practice of health care professions is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

^[1] Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1	INTRODUCTION	1
2	GOOD PRACTICE FRAMEWORK: PROCEDURES TO BE FOLLOWED.....	2
3	CLINICAL RESPONSIBILITY FOR DECISIONS.....	2
4	DIAGNOSIS AND PROGNOSIS	3
5	OPTIONS FOR TREATMENT	3
6	EMERGENCIES	3
7	CHOOSING BETWEEN OPTIONS: PATIENTS WHO CAN DECIDE FOR THEMSELVES	3
8	CHOOSING BETWEEN OPTIONS: PATIENTS WHO CANNOT DECIDE FOR THEMSELVES.....	5
9	WITHHOLDING TREATMENT DUE TO SCARCITY OF RESOURCES AND ALLOCATION OF SCARCE RESOURCES	6
10	COMMUNICATING DECISIONS.....	6
11	RECORDING DECISIONS	6
12	REVIEWING DECISIONS.....	7
13	AUDIT	7
14	CHILDREN.....	7

GUIDELINES FOR THE WITHHOLDING AND WITHDRAWING OF TREATMENT

1 INTRODUCTION

- 1.1 Health care practitioners have a responsibility to make the care of their patients their first concern. This is essential when considering any of the growing range of life-saving or life-prolonging treatments which make it possible to extend the lives of patients who, through organ or system failure, might otherwise die. The benefits of modern techniques such as cardiopulmonary resuscitation, renal dialysis, artificial ventilation, and artificial nutrition and hydration are considerable. However, life has a natural end and the existence of such techniques of life support may, in certain cases, sustain life artificially for many years for patients for whom there is little hope of recovery. The quality of life which may follow some treatments might raise questions as to whether it is in the best interests of the patient to start or continue treatment.
- 1.2 The guidance which follows is intended to provide an ethical framework of good practice for health care practitioners in circumstances where they are faced with making a decision on whether to withhold or withdraw life-prolonging treatment. It is based on those areas of broad consensus so far established and recognises the need to ensure that patients can die with dignity and that their families and others close to them are appropriately involved in their care. It takes account of existing law in this area, that allowing for withholding and withdrawing of life sustaining treatments and that which prohibits killing, active euthanasia, and assisted suicide. It is, therefore, based on the premise that any medical intervention where the health care professional's primary intention is to end the patient's life is both contrary to the ethics of health care and unlawful.
- 1.3 The health care professional may alleviate the suffering of a terminally-ill patient by withholding treatment, i.e. allowing the natural process of death to follow its course, provided there is consultation with another health care practitioner who is an expert in the field, and where available, discussions with the closest relatives. The withholding of treatment does not exempt the health care professional from the duty to assist the dying person by providing him or her with the necessary medication in order to alleviate the terminal phase of illness. The health care professional shall refrain from employing unusual methods of treatment which are of no benefit to the patient."
- 1.4 The HPCSA also expects health care practitioners to observe the provisions of the World Medical Association Declaration on Terminal Illness.
- 1.5 Health care practitioners have a duty to give priority to patients on the basis of clinical need, while seeking to make the best use of resources and using up to date evidence about the clinical efficacy of treatments. Health care practitioners must not allow their views about, for example, a patient's age, disability, race, colour, culture, beliefs, sexuality, gender, lifestyle, social or economic status or other irrational grounds to prejudice the choices of treatment offered or the general standard of care provided. A non-discriminatory policy also applies to patients infected with HIV. In any event a diagnosis of HIV infection, without further examination, provides only incomplete information about a person's prognosis or actual state of health.

2 GOOD PRACTICE FRAMEWORK:**PROCEDURES TO BE FOLLOWED**

- 2.1 The National Health Act (Act No. 61 of 2003) allows patients in writing to mandate a person to act on their behalf when they are no longer able to do so. Therefore, patients should be encouraged to appoint in writing a person to make decisions on their behalf when they are no longer capable of doing so. The patient-selected proxy decision-maker must then be regarded as the substitute for the patient whenever reference is made to the patient in these provisions.
- 2.2 Patients and their families, unless a contrary wish is expressed, must be kept informed of treatment, treatment alternatives and outcome probabilities.
- 2.3 Patients should be given the opportunity and be encouraged to indicate their wishes regarding further treatment and to place in writing their directives for future care in possible critical circumstances, (e.g. permanent coma or terminal illness). An appropriately drafted “living will” may be used for this purpose. These instructions can also be set out in the mandate to a third party mentioned in para 2.1 above. Patients should also be given the opportunity to reconsider their directives from time to time and to alter instructions, should they wish to do so.
- 2.4 When the patient is incapable of being involved in making a decision related to treatment and no advance directive or other information regarding the patient’s wishes is available, close family must be consulted and a decision taken in what are considered to be the patient’s best interests.
- 2.5 Before taking definitive action, the responsible health team should carefully consider and discuss the issue, obtain the advice of other health care practitioners, the family, patient (if possible) and a person with a background in ethics. Health care practitioners should always involve the family and patient (where practicable) in the discussions, and should never act in haste.
- 2.6 When the patient or the family request continued treatment against health advice that considers such treatment to be futile, the patient or the family must be given the choice of transferring to another institution where such treatment is available. If this option is refused and the health team considers treatment to be futile, and this is confirmed by an independent health care practitioner, treatment may be withheld or withdrawn.
- 2.7 All decisions should be fully and clearly documented in the notes, including the reasons for the decision and the procedure adopted in the decision-making process. Where significant disagreement arises about a patient’s best interests, health care practitioners should seek a clinical and / or ethical review, independent of the health care team. If this fails to resolve the disagreement, they must seek legal advice on whether it is necessary to apply to the court for a ruling.

3 CLINICAL RESPONSIBILITY FOR DECISIONS

A decision to withhold or withdraw life-prolonging treatment should be made only by the senior clinician in charge of a patient’s care, taking account of the views of the patient or those close to the patient.

4 DIAGNOSIS AND PROGNOSIS

Before a decision is made to withhold or withdraw treatment, the treating health care practitioner must carry out a thorough assessment of the patient's condition and the likely prognosis, taking account of current guidance on good clinical practice. The practitioner should always consider seeking a second opinion. Health care practitioners must seek a second opinion in cases where they are not sufficiently experienced or knowledgeable.

5 OPTIONS FOR TREATMENT

- 5.1 Health care practitioners should only identify treatment options as being appropriate if based on up-to-date clinical evidence about efficacy, side-effects and other risks, while also referring to any relevant clinical guidelines on the treatment and management of the patient's condition, or of patients with similar underlying risk factors.
- 5.2 Health care practitioners must reach a considered judgment on the likely benefits, burdens and risks (including non-clinical ones) for the particular patient of each of the treatment (or non-treatment) options identified. They should always consult a clinician with relevant experience in cases where:
- 5.2.1 The health care practitioner and the health care team have limited experience of a condition; or
- 5.2.2 The health care practitioner is in doubt about the range of options or the benefits, burdens and risks of a particular option for the individual patient; or
- 5.2.3 The health care practitioner is considering withholding or withdrawing artificial nutrition and hydration.

6 EMERGENCIES

- 6.1 In an acute life threatening emergency where any delay might prejudice the outcome and where it is impossible to obtain all relevant information or hold any consultations required - or where there is uncertainty about the diagnosis or the likelihood of recovery, health care practitioners should start treatment which may be of some benefit to the patient until a clearer assessment can be made.
- 6.2 If the treatment referred to in para 6.1 above, was done without the consent of the patient the health care practitioner should inform the patient about the procedures that were done – as soon as the patient is mentally capable of understanding such information.

7 CHOOSING BETWEEN OPTIONS: PATIENTS WHO CAN DECIDE FOR THEMSELVES

7.1 SEEKING THE PATIENT'S VIEWS

- 7.1.1 Where a patient is competent to participate in decision-making, health care practitioners must discuss with the patient their conclusions about diagnosis, prognosis and which options they consider may be in the patient's best interests. It is for the patient to judge what might be acceptable; what weight or priority to give to any burden or risks; and to decide which of the options would be in his or her best interests.

- 7.1.2 Health care practitioners should bear in mind that the decisions of competent adult patients to refuse a particular medical intervention must be respected, even where this would result in serious harm to them or in their own death.
- 7.1.3 Where the possibility of withholding or withdrawing of life-prolonging treatment is being considered as an option, health care practitioners should discuss with the patient how his or her care would be managed if such a decision were made. This should include arrangements for providing basic care and other appropriate treatment; and what might be his or her palliative or terminal care needs and how these would be met. In addition the patient's preferences about who should be involved in decision-making or in providing additional support if he or she becomes incapacitated should also be discussed.
- 7.1.4 Discussions of the sort in the above paragraph will allow patients the opportunity they need to decide what arrangements should be made to manage the final stages of their illness; and to attend to personal and other concerns which are important in ensuring that patients can die with dignity.
- 7.1.5 Discussions about the possibility of withholding or withdrawing a potentially life-prolonging treatment may be difficult and distressing. However, this does not mean that such discussions should be avoided. Instead, the discussions should be handled sensitively and with appropriate support being provided to the patient. Health care practitioners should also consult with those close to the patient about the best means of withholding or withdrawing treatment where this is appropriate.
- 7.1.6 Where patients clearly indicate that they do not wish to know or discuss the details, health care practitioners should still provide the patient with sufficient information about his or her condition and its treatment to enable the patient to make an informed decision.
- 7.1.7 A linguistic or cultural barrier may exist between health care practitioners and the patient. Under these circumstances, an interpreter fluent in the language used by the patient should be present in order to facilitate communication when discussions are held and decisions regarding the treatment of the patient are to be made.

7.2 TIMING OF DISCUSSIONS WITH THE PATIENT

- 7.2.1 Health care practitioners should hold discussions at a time when the patient is best able to understand and retain information. They should allow the patient sufficient time to reflect and ask questions before deciding.
- 7.2.2 Health care practitioners should also discuss the patient's right to change his or her mind about the decision. Where a patient has an existing condition and the likely progression of the disorder is known, the health care practitioner should consider formulating an advance management plan with the patient and the clinical team.

8 CHOOSING BETWEEN OPTIONS: PATIENTS WHO CANNOT DECIDE FOR THEMSELVES

8.1 ASSESSING CAPACITY TO DECIDE

- 8.1.1 In most cases where the dying process itself affects the patient's mental capacity, the correct course of action for the patient should have been decided previously. Where no such advance management plan had been agreed, or the plan has not been reviewed recently, or is not relevant to the patient's current condition, health care practitioners are advised as follows:
- 8.1.2 Where patients have difficulty retaining information, communicating their views, or are only intermittently competent, health care practitioners should provide any assistance a patient might need to enable him or her to reach and communicate a decision.
- 8.1.3 Where there are doubts about a patient's capacity at making a decision, health care practitioners should consult with the relevant health care practitioner taking into account any legal tests of capacity.

8.2 MAKING DECISIONS FOR THE PATIENT

- 8.2.1 Where a patient lacks the capacity to decide, health care practitioners must respect any valid advance refusal of treatment.
- 8.2.2 Where there is no advance refusal of treatment the senior clinician responsible for the patient's care must make the decision about what course of action would be in the patient's best interests:
- 8.2.2.1 The senior clinician should consult the patient's authorised representative if such a person was appointed.
 - 8.2.2.2 The clinician should also consult the health care team and the patient's authorised representative and, wherever possible, those close to the patient. The latter may be able to provide insights into the patient's preferences, and be able to offer an opinion on what would be in the patient's best interests.
 - 8.2.2.3 Health care practitioners should pay due regard to any previous wishes of the patient about not disclosing information to particular individuals.
 - 8.2.2.4 If the patient is new to the health care practitioner at the time decisions are needed, the health care practitioner must satisfy himself or herself whether or not such consultations have previously been carried out and if so, find out what had been agreed.
- 8.2.3 The health care practitioner should consider what support could be provided to family members and others close to the patient.

8.3 REACHING CONSENSUS

The consultations between the clinician and the health care team and those close to the patient should aim to achieve consensus on what course of action would be in the best interests of the patient. The factors considered in assessing best interests should take into account guidance from the HPCSA, pertinent ethical principles and relevant statutory requirements,

9 WITHHOLDING TREATMENT DUE TO SCARCITY OF RESOURCES AND ALLOCATION OF SCARCE RESOURCES

- 9.1 There are circumstances when withholding treatment, even if it is not in the best interest of the patient is permissible. This will apply to continued care in special units such as critical care and chronic dialysis units for end stage kidney failure.
- 9.2 A health care institution has the right to limit life-sustaining interventions without the consent of a patient or surrogate by restricting admission to these units. However, such restriction must be based on national admission criteria agreed upon by the expert professional bodies in the relevant speciality, as well as the HPCSA.
- 9.3 A health care institution is, however, obliged to provide the appropriate palliative care and follow up when specialised care is withheld.
- 9.4 If, however, the patient does satisfy all the criteria for admission, but cannot be admitted because of limited resources at a particular institution, the health care practitioner must transfer the patient to another institution where such resources exist. However, this should be done only after the necessary emergency treatment has been instituted.
- 9.5 The HPCSA considers it unethical to continue with life-prolonging treatment for the sole purpose of financial gain. Moreover, it is unacceptable that patients are transferred to state institutions after all their funding has been exhausted as a result of prolonging futile treatments.

10 COMMUNICATING DECISIONS

- 10.1 Whatever decision is made, health care practitioners must ensure that all those consulted, and especially those responsible for delivering care, are informed of the decision and are clear about the goals and the agreed management plan.
- 10.2 It is particularly important where treatment is to be withheld or withdrawn that everyone involved is clear about the arrangements for providing appropriate palliative or terminal care and about their own roles.
- 10.3 Health care practitioners should discuss what the role of the family or other carers will be and what support they will receive from the health care team.

11 RECORDING DECISIONS

- 11.1 Health care practitioners must ensure that decisions are properly documented, including the relevant clinical findings; details of discussions with the patient, health care team or others involved in decision-making; and details of treatment or other significant factors which may affect future care.
- 11.2 Health care practitioners should record the information at the time of the events described or soon thereafter. The record should be legible, clear, accurate and

unambiguous. It should, for example, avoid abbreviations or other terminology that may cause confusion to those providing care.

- 11.3 Health care practitioners should ensure that the records are appropriately accessible to team members and others involved in providing care to the patient.

12 REVIEWING DECISIONS

- 12.1 Health care practitioners must review their decisions at appropriate intervals during the agreed treatment or the period of palliative or terminal care to determine whether the goals of treatment or the management plan remain appropriate.
- 12.2 Health care practitioners should seek a second opinion where, for example the patient's condition is not progressing as expected.

13 AUDIT

- 13.1 As in other areas of decision making, health care practitioners must carry out clinical audits of the process which can improve their own and others' knowledge about the outcomes of different treatment and non-treatment decisions.
- 13.2 Where possible health care practitioners should help to disseminate best practice, for example, by contributing to the education of students and colleagues about good practice in the area concerned.

14 CHILDREN

- 14.1 The general principles of good practice set out in this framework also apply to decision-making in cases involving children - including premature babies where the decisions may be particularly difficult for everyone involved.
- 14.2 Health care practitioners should respect the decisions of children who have the legal capacity to make decisions about refusing health care – except in cases where the practitioners believe that it is not in the child's best interests – in which case they should approach the court for a decision.
- 14.3 In all cases, health care practitioners and others who make decisions on behalf of a child have to consider only those options that are in the best interest of the child.
- 14.4 If the child does not have the legal capacity to make a decision, but is sufficiently mentally mature to understand the procedures to be adopted, he or she should be consulted during the decision-making process.

ANNEXURE**World Medical Association Declaration on Terminal Illness**

Adopted by the 35th World Medical Assembly Venice, Italy, October 1983
and Revised by the WMA General Assembly, Pilanesberg, South Africa, October 2006

Preface

1. When addressing the ethical issues associated with end-of-life care, questions regarding euthanasia and physician-assisted suicide inevitably arise. The World Medical Association condemns as unethical both euthanasia and physician-assisted suicide. It should be understood that WMA policy on these issues is fully applicable in the context of this Statement on Terminal Illness.

Preamble

2. When a patient's medical diagnosis precludes the hope of health being restored or maintained, and the death of the patient is inevitable, the physician and the patient are often faced with a complex set of decisions regarding medical interventions. Advances in medical science have improved the ability of physicians to address many issues associated with end-of-life care. However, it is an area of medicine that historically has not received the attention it deserves. While the priority of research to cure disease should not be compromised, more attention must be paid to developing palliative treatments and improving the ability of physicians to assess and address the medical and psychological components of symptoms in terminal illness. The dying phase must be recognized and respected as an important part of a person's life. As public pressure increases in many countries to consider physician assisted suicide and euthanasia as acceptable options to end suffering in terminal patients, the ethical imperative to improve palliative treatment in the terminal phase of life comes into sharp focus.
3. The World Medical Association recognizes that attitudes and beliefs toward death and dying vary widely from culture to culture and among different religions. In addition, many palliative and life-sustaining measures require technologies and/or financial resources that are simply not available in many places. The approach to medical care of the terminally ill will be influenced significantly by these factors, and thus attempting to develop detailed guidelines on terminal care that can be universally applied is neither practical nor wise. Therefore, the World Medical Association articulates the following core principles to assist physicians and National Medical Associations with decision-making related to terminal care.

Principles

4. The duty of physicians is to heal, where possible, to relieve suffering and to protect the best interests of their patients. There shall be no exception to this principle even in the case of incurable disease.
5. In the care of terminal patients, the primary responsibilities of the physician are to assist the patient in maintaining an optimal quality of life through controlling symptoms and addressing psychosocial needs, and to enable the patient to die with dignity and in comfort. Physicians should inform patients of the availability, benefits and other potential effects of palliative care.
6. The patient's right to autonomy in decision-making must be respected with regard to decisions in the terminal phase of life. This includes the right to refuse treatment and to request palliative measures to relieve suffering but which may have the additional effect of accelerating the dying process. However, physicians are ethically prohibited

from actively assisting patients in suicide. This includes administering any treatments whose palliative benefits, in the opinion of the physician, do not justify the additional effects.

7. The physician must not employ any means that would provide no benefit for the patient.
8. . Physicians should recognise the right of patients to develop written advance directives that describe their wishes regarding care in the event that they are unable to communicate and that designate a substitute decision-maker to make decisions that are not expressed in the advance directive. In particular, physicians should discuss the patient's wishes regarding the approach to life-sustaining interventions as well as palliative measures that might have the additional effect of accelerating death. Whenever possible, the patient's substitute decision-maker should be included in these conversations.
9. Physicians should endeavour to understand and address the psychosocial needs of their patients, especially as they relate to patients' physical symptoms. Physicians should try to ensure that psychological and spiritual resources are available to patients and their families to help them deal with the anxiety, fear and grief associated with terminal illness.
10. The clinical management of pain in terminal patients is of paramount importance in terms of alleviating suffering. Physicians and National Medical Associations should promote the dissemination and sharing of information regarding pain management to ensure that all physicians involved in terminal care have access to best practice guidelines and the most current treatments and methods available. Physicians should be able to pursue clinically appropriate aggressive pain management without undue fear of regulatory or legal repercussions.
11. National Medical Associations should encourage governments and research institutions to invest additional resources in developing treatments to improve end-of-life care. Medical school curricula should include the teaching of palliative medical care. Where it does not exist, the establishment of palliative medicine as a medical specialty should be considered.
12. National Medical Associations should advocate for the development of networks among institutions and organizations involved in palliative care in order to foster communication and collaboration
13. Physicians may, when the patient cannot reverse the final process of cessation of vital functions, apply such artificial means as are necessary to keep organs active for transplantation provided that they act in accordance with the ethical guidelines established in the World Medical Association Declaration of Sydney on the Determination of Death and the Recovery of Organs.



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

**GENERAL ETHICAL GUIDELINES FOR
REPRODUCTIVE HEALTH**

BOOKLET 8

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcsah@hpcsah.co.za

Website: <http://www.hpcsah.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care professional requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practice as a health care professional is a moral enterprise. In this spirit the Health Professions Council of South Africa presents the following ethical guidelines.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1. PREAMBLE.....	5
2. THE ROLE OF THE HEALTH PRACTITIONERS AS ADVOCATES FOR.....	6
 WOMEN’S HEALTH	6
3. INTIMATE EXAMINATIONS	5
4. VIOLENCE AGAINST WOMEN	8
5. DOMESTIC VIOLENCE.....	8
6. CONTRACEPTION	10
7. ETHICAL CONSIDERATIONS IN STERILIZATION	11
8. INDUCED ABORTION FOR NON-HEALTHCARE PRACTITIONER REASONS	13
9. SEX SELECTION.....	14
10. SURROGATE MOTHERHOOD	14
11. PREVENTING IATROGENIC MULTIPLE PREGNANCY	15
12. ETHICAL GUIDELINES REGARDING THE PROCEDURE	15
 OF COLLECTION OF CORD BLOOD.....	15

1. PREAMBLE

The concept of reproductive health will play a crucial role in improving women's health and rights in the country. While reproductive health is an important component of health for both women and men, it is more critical, however, for women. A major burden of disease in females is related to their reproductive function and reproductive potential, and the way in which society treats or mistreats women because of their gender. The concept of reproductive health offers a comprehensive and integrated approach to health needs related to reproduction. It puts women at the centre of the process, and recognizes respects and responds to the needs of women¹. Women have a unique vulnerability because of their reproductive function and role. Social discrimination and abuse based on gendered undervaluing of women may further compromise women's health. Concern for family welfare may take precedence over individual health and also increase their health risk. However, whatever the social norms, these should not be allowed to impact negatively on women's health.

The concept of reproductive health received great attention and was endorsed at the United Nations International Conference on Population and Development held in Cairo in 1994. The definition of reproductive health adopted at the conference reads as follows:

"Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how to do so. Implicit in this last condition are the right of men and women to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice, as well as other methods of their choice for regulation of fertility which are not against the law, and the right of access to appropriate health care service that will enable women to go safely through pregnancy and childbirth.."² This would serve to provide women with the best chance of having a healthy infant.

In the delivery of health care to women, justice requires that all women are treated with equal consideration, irrespective of their socioeconomic status³. Allocation must therefore be based on clinical needs and be in line with the Bill of Rights of the Constitution. Moreover, women's rights to bodily integrity must always be respected and the unequal power relationship between men and women must be taken into account when facilitating women in making their own choices.

1. Cook RJ, Dickens BM, Fathalla MF eds. Reproductive Health and Human Rights. Oxford University Press. 2003.
2. UN Department of Public Information, Platform For Action and Beijing Declaration. Fourth World Conference on Women, Beijing, China, 4-15 September 1995. (New York: UN, 1995), Para94.
3. November 2003. Recommendations on Ethical Issues in Obstetrics and Gynaecology by the FIGO Committee on the Ethical Aspects on Human Reproduction and Women's Health. <http://www.figo.org>. These guidelines have in the main been drawn from the FIGO recommendations.

2. THE ROLE OF THE HEALTH PRACTITIONERS AS ADVOCATES FOR WOMEN'S HEALTH

As advocates for women's health:

- 2.1 Health practitioners have an ethical duty to be advocates for women's health care. The HPCSA places an obligation on health practitioners to advocate for improvements in the health and social status of women. This is because the knowledge base and social standing of practitioners places them in a position with potential to influence policies regarding women's health.
- 2.2 Health practitioners are obliged individually and as a profession to monitor and publicise indices of reproductive health and provide data to sensitise the public to health issues and rights of women. The informative function should not be limited to quantifying the problem, but they should also identify social and cultural causes in order to develop appropriate strategies for improvement.
- 2.3 Failure to advocate policies that will improve women's health care and advance women's rights broadly will deleteriously influence the health care of the individual patients.
- 2.4 Practitioners should inform the community about problems of sexual and reproductive health and promote a wide debate in order to influence health practices and legislation. The debate should include a broad spectrum of society such as healthcare practitioner associations, women's organizations, legislators and educators. Health professionals are also obliged to organize themselves and other professional groups to ensure that essential health services are available for disadvantaged, impoverished and underprivileged women.

3. INTIMATE EXAMINATIONS²

Complaints of sexual impropriety against health care practitioners are escalating. Professionalism in the practitioner-patient relationship and the role-based trust in health care do not allow crossing of sexual boundaries. Communication with patients is key to prevent erroneous allegations of sexual misconduct. The intimate examination is difficult to define. A chaperone present during an intimate examination protects the patient and practitioner and should be considered a risk reduction strategy in practice.

² This section is based on extracts from Ames Dhai, Jillian Gardner, Yolande Guidozzi, Graham Howarth, Merryl Vorster "Professionalism and the intimate examination – are chaperones the answer?" *S Afr Med J* 2011;110:814-816.

- 3.1 Sexual misconduct may be categorised as “sexual impropriety” Behavior, gestures or expressions that are sexually suggestive, Seductive or disrespectful of a patient’s privacy or sexually demeaning to a patient; and “sexual violation” refers to physical sexual contact between a doctor and a patient, whether or not it was consensual and/or Initiated by the patient.
- 3.2 The Healthcare practitioner Protection Society (MPS) defines intimate examinations as including, but not limited to, examination of the breasts, genitalia and rectum, and any examination where it is necessary to touch the patient in close proximity, and cautions practitioners to be vigilant in situations of vulnerability, e.g. when listening to the chest, taking blood pressure using a cuff and palpating the apex beat, as these could involve touching the breast area.
- 3.3 Sexual involvement with a patient could affect the practitioner’s healthcare practitioner judgment and thereby harm the patient. Sexual relationships between patients and practitioners are considered unethical and a form of professional misconduct by the HPCSA. Because of the unequal power relationship and the dependence of the patient on the practitioner, even a consenting sexual relationship does not relieve the practitioner of the HPCSA’s ethical prohibition.
- 3.4 The following framework for the conduct of intimate examinations is recommended:
 - i. Ensure the intimate examination is necessary and will assist in the patient’s care.
 - ii. Explain to the patient that an intimate examination needs to be done and why.
 - iii. Explain what the examination will involve.
 - iv. Obtain the patient’s permission - verbal permission and the co-operation of the patient to adopt an appropriate state of undress and position may provide sufficient authorisation.
 - v. Offer all patients who are to undergo intimate examination a chaperone, irrespective of the gender of the practitioner.
 - vi. Should the patient wish to have a chaperone, the presence of the chaperone and the chaperone’s identity should be noted at the time.
 - vii. Should the patient decline a chaperone, this should be noted at the time.

- viii. Should the patient decline the offer of a chaperone and the practitioner prefers to have one present, this should be communicated to the patient. If the patient still declines the offer of a chaperone, the practitioner should probably not perform the examination.
- ix. Give the patient privacy to undress and dress.
- x. Adequate and appropriate draping should be used when the patient is undressed.
- xi. Keep the discussion relevant and avoid unnecessary personal comments.
- xii. Encourage questions and discussion.

4. VIOLENCE AGAINST WOMEN

Violence against women is a reflection of the unequal power relationship of men and women in societies. The HPCSA condemns violence against women, whether it occurs in a societal setting (such as virginity testing) or a domestic setting (such as spousal abuse). It is not a private or family matter. Violence against women is not acceptable whatever the setting and therefore practitioners treating women are ethically obligated to:

4.1 Inform themselves about the manifestations of violence and recognize cases. Documentation must take into account the need for confidentiality to avoid potential harmful consequences for the woman, and this may need separate, non-identifiable compilation of data.

- i. Treat the physical and psychological results of the violence.
- ii. Affirm to their patients that violent acts towards them are not acceptable.
- iii. Advocate for social infrastructures to provide women the choice of seeking secure refuge and ongoing counselling.

4.2 The physical, financial and social vulnerabilities of women are fundamentally harmful to the future of a society. Not redressing them fails to prevent harm to subsequent generations and contributes to the cycle of violence. Practitioners treating women therefore have an obligation to:

- i. Affirm women's rights to be free of physical and psychological violence, particularly sexual violence including sexual intercourse without consent within marriage.
- ii. Advocate for non-violent resolutions in relationships by Enlisting the aid of social workers and other health care workers where appropriate.
- iii. Make themselves and others, in particular men, aware of the

harmful effects of the embedded discrimination against women in social systems.

4.3 There is a need for wider awareness of the magnitude of the problem of violence against women. Practitioners are uniquely placed to assist in this. Only if a problem is recognized can it be addressed. There is therefore a duty for professional societies and practitioners to publicize information about the frequency of types of violence against women.

5. DOMESTIC VIOLENCE³

5.1 “Domestic violence” is defined by the Domestic Violence Act as: “Any controlling, abusive, fear-inducing act that threatens to harm the health, well-being or safety of a person in a domestic relationship” , while the United Nations defines it as: “Any act of gender-based violence that results in, or is likely to result in, physical, sexual or psychological harm or suffering to women, including threats of such acts, coercion or arbitrary deprivations of liberty, whether occurring in public or private life”. Domestic Violence is a form of Gender-based violence or interpersonal violence and does not preclude men and children as victims.

5.2 According to the United Nations “Gender-based violence” is any harmful act that is perpetrated against a person’s will and that is based on socially ascribed (gender) differences between males and females and is usually regarded as interchangeable with “violence against women.” It highlights the relationship between the subordinate status of women in society and their increased vulnerability to violence. Men and boys may also be survivors of gender-based violence, especially sexual violence.

5.3 Health care professionals must be responsive to domestic violence by the following actions:

- I. Screening: Ask gently about violent and/or controlling behavior and believe response.
- ii. Assess Risk: Conduct a risk assessment in all cases of domestic violence to identify imminent danger – especially where the patient still has contact with the perpetrator.
- iii. Supportive care: Provide supportive bio-psycho-social care.
- iv. Document: Document any evidence of abuse on a Domestic Violence examination form.
- v. Inform: Inform patients of their rights, services and the legal remedies, including how to obtain a protection order under the Domestic Violence Act, and whether they want to report the case to the police. Explain the implications of domestic

³ Based on the Domestic Violence Screening Protocol Prepared by the Professional Board for Emergency Care.

violence, including the risk of HIV and in the case of a sexual offence their right to get free HIV treatment under the Sexual Offences Act.

- vi. Refer responsibly: Refer clients to appropriate resources and identify their support system.

5.4 When conducting a risk assessment in situations where the patient is uncertain about reporting continued dangerous domestic violence to the police, health care professionals should establish the following in order to develop a safety plan:

- i. Has the violence increased?
- ii. Does the perpetrator use alcohol and drugs?
- iii. Has the perpetrator threatened to kill the patient?
- iv. Does the perpetrator have access to weapons?
- v. Is the patient afraid to go home?
- vi. Has the patient or perpetrator thought about killing themselves?

6. CONTRACEPTION

Women have the right to make a choice on whether or not to reproduce and should therefore have access to legal, safe, effective and affordable methods of contraception. Responsible control of procreation enjoys wide social acceptance. However, none of the current methods of fertility control fully satisfies the ideal of safety, effectiveness, reversibility, ease and religious acceptance. Contraceptive counseling and the rendering of contraceptive care are clear examples of healthcare practitioner care requested for other than the treatment of disease.

- 6.1 The principle of beneficence requires that contraceptive methods must be safe, effective, and acceptable to women.
- 6.2 In introducing contraceptive methods, healthcare practitioner practitioners must be guided by respect for an individual's autonomy.
- 6.3 The same respect for autonomy requires that standards especially relevant to the introduction of methods of fertility regulation should include both facilitating informed choice and delivering quality care.

- 6.4 There are 2 major aspects to delivering quality of care: healthcare practitioner quality requirements and the need to take into account the woman's express wishes. Healthcare practitioner quality requirements include that a range of appropriate contraceptive methods is offered, that appropriate support counseling services are available and that providers are technically competent. Interpersonal relations with healthcare personnel must be respectful and take into account women's inputs and opinions.
- 6.5 Nobody may refuse to sell condoms to a child over the age of 12 years, or provide a child over the age of 12 years with condoms on request where condoms are provided or distributed free of charge (Children's Act, 2005 section 134(1)) .
- 6.6 Contraceptives other than condoms may be provided to a child on request by the child and without the consent of the parent or care-giver of the child if the child is at least 12 years of age, proper medical advice is given to the child, and a medical examination is carried out on the child to determine whether there are any medical reasons why a specific contraceptive should not be provided to the child (Children's Act, 2005 section 134(2)).
- 6.7 A child who is legally competent to obtain condoms, contraceptives or contraceptive advice entitled to confidentiality in this respect (Children's Act, 2005 section 134(3)).

7. ETHICAL CONSIDERATIONS IN STERILIZATION

Decisions about sterilization involve personal values and therefore may be subject to inappropriate practitioner bias. Ethical considerations evolve from these unique and controversial aspects of fertility control.

Sterilization differs from other contraceptive methods because in theory it eliminates any further option to procreate. The intention of permanency underscores the need for patients and practitioners to consider a special set of ethical issues and the well-documented possibility of later regret by the patient

The obvious relationship of sterilization to procreation, the potential irreversibility of the procedure, and its usually elective nature require that certain ethical considerations receive special emphasis. Although these considerations involve matters of private and individual choice, they may also have societal implications.

7.1 Specific ethical considerations in sterilization

- 7.1.1 Because a patient's ability to procreate may significantly affect the lives of others, the practitioner should encourage the patient to include other appropriate persons including her partner in the counseling process. However, the partner's consent must not be obligatory.

- 7.1.2 The withholding of other healthcare practitioner care by linking it to the patient's agreement to undergo sterilization is coercive and unacceptable.
- 7.1.3 The physician's personal values or sense of societal objectives should never be a basis for urging sterilization. Ethnic, racial or socioeconomic factors should never be grounds for limiting a patient's choices about sterilization.
- 7.1.4 The physician's personal values should not limit counseling, services or referral.
- 7.1.5 The rights of mentally handicapped and other vulnerable persons, whether institutionalized or not, should be carefully protected. Even if a person is unable to make their own decision because of mental incapacity or mental retardation, nevertheless they must be involved in the decision-making process to the fullest extent their capacity allows, and their best interests must be taken into account.
- 7.1.6 Hysterectomy solely for the purpose of sterilization is inappropriate because of the disproportionate risks and costs.
- 7.1.7 Special informed consent considerations inherent in sterilization counselling include:
- a) Sterilization is intended to be permanent;
 - b) Life circumstances may change;
 - c) The patient may later regret her sterility;
 - d) Male sterilization may be an appropriate alternative;
 - e) There is a measurable failure rate with any sterilization procedure.
- 7.1.8 No minimum or maximum number of children may be used as a criteria for access to sterilisation.
- 7.1.9 At a public policy level, the profession has a duty to be a voice of reason and compassion, pointing out when legislative and regulatory measures interfere with personal choice and appropriate healthcare practitioner care.
- 7.1.10 Practitioners may also encounter situations in which, according to their best judgement, sterilization would not be appropriate. It is the right of these practitioners to abstain from the performance of the sterilizing procedures.

(See the Sterilization Act No 44 of 1998)

- 7.1.11 In terms of the Constitution practitioners may refuse to participate in a sterilization procedure because of their conscience or religious beliefs

(Constitution of the Republic of South Africa, 1996 section 15) provided it is not an emergency situation.

8. TERMINATION OF PREGNANCY FOR NON-MEDICAL REASONS

- 8.1 Abortion is very widely considered to be ethically justified when undertaken for medical reasons to protect the life and health of the mother.
- 8.2 The use of abortion for other social reasons remains very controversial because of the ethical dilemmas it presents to both women and the healthcare team. Women frequently agonise over their difficult choice, making what they regard in the circumstances to be the least worst decision. Health care providers wrestle with the moral values of preserving life, of providing care to women and of avoiding unsafe abortions.
- 8.3 Every effort must be made to improve women's rights, status and health and to prevent unintended pregnancies by education, counseling, making available reliable information and services on family planning. Abortion should never be promoted as a method of family planning.
- 8.4 Providing the process of a properly informed consent has been carried out a woman's right to autonomy coupled with the need to prevent unsafe abortion, justifies the provision of safe abortion.
- 8.5 Where practitioners feel that abortion for non-healthcare practitioner reasons is not permissible whatever the circumstances, respect for their autonomy means that they should not be expected to advise or perform abortions against their personal convictions. Their careers should not be prejudiced as a result. Such practitioners are obliged to refer the woman to a colleague who is not in principle opposed to the abortion.
- 8.6 Practitioners do not have the right to impose their religious or cultural convictions regarding abortion on those whose attitudes are different. Counseling should include objective information. Post abortion counseling on fertility control should always be provided.
- 8.7 After appropriate counseling, a woman has the right to have access to healthcare practitioner or surgically induced abortion, and the health care service has an obligation to provide such services as safely as possible.
- 8.8 A female child of any age is legally competent to consent to a termination of pregnancy (Choice on Termination of Pregnancy Act, 1996 (Act No. 92 of 1996)) provided she has the necessary mental capacity to give an informed consent by understanding and

appreciating the benefits, risks, social and other implications of the termination of pregnancy.

- 8.9 Practitioners are urged to facilitate access by female children seeking a termination of pregnancy to appropriate non-directive education, counseling and family planning services.

9. SEX SELECTION

Deeply-rooted discrimination based on gender and sex is still prevalent in many societies. Selective abortion of a fetus based on gender (e.g female fetus) is another manifestation of this social injustice.

- 9.1 The ethical principles of protection of the vulnerable and justice are violated by sex selection abortion (whether male or female). No fetus should be sacrificed because of its sex alone.
- 9.2 The use of preconceptional sex selection to avoid sex-linked genetic disorders is completely justifiable on healthcare practitioner grounds.
- 9.3 Preconceptional sex selection should never be used as a tool for sex discrimination against either sex, especially female.

10. SURROGATE MOTHERHOOD

- 10.1 Surrogacy can be applied only in cases of very limited special indications.
- 10.2 Special attention has to be made to the ethical principle of protection of the surrogate mother who can be exploited because of her socioeconomic status.
- 10.3 The autonomy of the surrogate mother should be respected and the surrogate arrangement should not be commercialized.
- 10.4 Surrogacy should be practiced strictly under healthcare practitioner supervision, taking into consideration full regard of ethics and the law. Participants should be fully informed of the legal position.
- 10.5 All surrogacy agreements must be approved by the High Court (Children's Act No. 38 of 2005, section 292) and practitioners should ensure that this has been done before engaging in surrogacy procedures.
- 10.6 In terms of the Constitution practitioners may refuse to participate in a surrogacy procedure because of their conscience or religious beliefs (Constitution of the Republic of South Africa, 1996 section 15) provided it is not an emergency situation.

11. PREVENTING IATROGENIC MULTIPLE PREGNANCY

The use of ovulation inducing drugs and of multiple embryo transfer in the treatment of infertility has led to a dramatic increase in multiple pregnancies. The need for infertility treatment has also been rising sharply due to factors which include the trend towards pregnancy at later ages, and the impact of sexually transmitted diseases.

- 11.1 Multiple pregnancy has very serious implications for the mother and her offspring, for the family and the community, and for health service resources.
- 11.2 The misuse of drugs for the induction of ovulation is responsible for a great deal of iatrogenic multiple pregnancies. Therefore those prescribing these drugs should be appropriately trained and familiar with the indications for their use, their adverse side effects, and the methods of monitoring and preventing iatrogenic multiple pregnancy.
- 11.3 Assisted reproductive technologies whether by the induction of ovulation, transfer of gametes, pre-embryos or embryos should only be performed by those practitioners qualified to do so and should aim to achieve singleton pregnancies. Under optimal conditions, not more than two pre-embryos or embryos should be transferred.
- 11.4 Centers offering assisted reproductive technologies should be accredited to ensure a uniformly high standard.
- 11.5 The risks for both mother and her resulting children with triplets and higher order pregnancies are sufficiently great to justify consideration by the couple and their healthcare practitioner advisors of the use of fetal reduction.
- 11.6 Couples seeking treatment for infertility must be fully informed of the risks of multiple pregnancy both to the woman and to their potential progeny.

12. ETHICAL GUIDELINES REGARDING THE PROCEDURE OF COLLECTION OF CORD BLOOD

The discovery that umbilical cord-blood provided a rich source of haemopoietic stem cells used in transplantation in diseases such as leukaemia, has led to the organised collection of blood from this source and its retention in cord-blood banks until required. Altruistic non directed donations for public cord blood storage is currently not practiced in South Africa. Directed donations can be for "at risk families or "low risk families". No major controversy exists regarding directed donations in "at risk families". However, with "low risk families" the chance of using personal cord blood before the age of 20 years is low with estimates varying between 1 in 2 700 and 1 in 20 000. Currently, it is very expensive to store umbilical cord blood in

private banks. Hence, patients end up compromising themselves financially as the likelihood of them ever requiring the cells is very low. The vulnerability of parents at this emotional period in their lives need to be recognized and protected. Any advertising and marketing of cord blood storage must be done responsibly and must not exploit parents' vulnerabilities.

- 12.1 It is ethically necessary for the mother to give informed consent (before delivery) for the collection of cord-blood for banking where indicated.
- 12.2 The information that blood in the placenta is no longer of use to the baby and this "waste blood" may help to save another person's life is incomplete and does not permit informed consent.
- 12.3 The **timing of informed consent** from the mother is crucial in order to ensure an understanding and appreciation of the procedure. Moreover, she needs to be made aware of not only the benefits of the collection but also the associated risks which include the possibility of insufficient harvesting of the stem cells and the chance of using the blood before the age of 20 may be very low. Accordingly, consent should be taken early in the antenatal period. The taking of informed consent during active labour and delivery does not lend itself to an ethically and legally valid and binding decision. Moreover, during this confusing and emotional period the ability of the woman to make a rational decision is highly unlikely.
- 12.4 Early clamping of the umbilical cord following vaginal delivery is likely to deprive the newborn infant of at least a third of its normal circulating blood volume, and it will also cause a haemodynamic disturbance. These factors may result in serious morbidity.
- 12.5 For consent to be informed the harmful effects of early cord clamping should be disclosed and the mother assured that the collection of cord-blood will not involve early clamping.
- 12.6 Permission to collect blood from the cord for banking should not lead to clamping of the cord earlier than 20-30 seconds after delivery of the baby.
- 12.7 Any payment to the health care practitioner by the company for cord blood collection is viewed by the HPCSA as a "finder's fee" and therefore unethical.
- 12.8 There should be no alteration on the usual management of the third stage of labour
- 12.9 The HPCSA advises that there is insufficient evidence to recommend directed cord blood collection and storage in "low risk families". Hence, private cord blood banking cannot be recommended as a routine for everyone.



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

GUIDELINES ON THE KEEPING OF PATIENT RECORDS

BOOKLET 9

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcsa@hpcsa.co.za

Website: <http://www.hpcsa.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, the practice of health care professions is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1	DEFINITION OF A HEALTH RECORD	1
2	WHAT CONSTITUTES A HEALTH RECORD?	1
3	WHY DOCUMENTS OR MATERIALS SHOULD BE RETAINED	1
4	COMPULSORY KEEPING OF RECORDS	2
5	SIGNING OF OFFICIAL DOCUMENTS	2
6	CERTIFICATES AND REPORTS.....	3
7	ISSUING OF PRESCRIPTIONS.....	3
8	ALTERATION OF RECORDS.....	4
9	DURATION FOR THE RETENTION OF HEALTH RECORDS.....	4
10	OWNERSHIP OF RECORDS.....	5
11	ACCESS TO RECORDS.....	6
12	RETENTION OF PATIENT RECORDS ON CD-ROM	7
13	CHECKLIST FOR HEALTH RECORD-KEEPING.....	7

GUIDELINES ON THE KEEPING OF PATIENT RECORDS

These guidelines are applicable to health care practitioners in private practice (including managed health care organisations), as well as to those in the employ of the public service.

1. DEFINITION OF A HEALTH RECORD

A health record may be defined as any relevant record made by a health care practitioner at the time of or subsequent to a consultation and / or examination or the application of health management.²

A health record contains the information about the health of an identifiable individual recorded by a health care professional, either personally or at his or her direction.³

2. WHAT CONSTITUTES A HEALTH RECORD?

2.1 The following documents can be regarded as the essential components of a health record, obviously depending on the nature of the individual case:

2.1.1 Hand-written contemporaneous notes taken by the health care practitioner.

2.1.2 Notes taken by previous practitioners attending health care or other health care practitioners, including a typed patient discharge summary or summaries.

2.1.3 Referral letters to and from other health care practitioners.

2.1.4 Laboratory reports and other laboratory evidence such as histology sections, cytology slides and printouts from automated analysers, X-ray films and reports, ECG traces, etc.

2.1.5 Audiovisual records such as photographs, videos and tape-recordings.

2.1.6 Clinical research forms and clinical trial data.

2.1.7 Other forms completed during the health interaction such as insurance forms, disability assessments and documentation of injury on duty.

2.1.8 Death certificates and autopsy reports.

2.2 The above records may be archived on microfilm, microfiche or magnetic data files.

3. WHY DOCUMENTS OR MATERIALS SHOULD BE RETAINED

3.1 Documents and materials should be retained in order to:

3.1.1 Further the diagnosis or ongoing clinical management of the patient;

3.1.2 Conduct clinical audits;

3.1.3 Promote teaching and research;

² de Klerk A. The right of patients to have access to their medical records: the position in South African law. *Medical Law*, Vol 12, 1993, pp. 77 - 83

³ *Making and keeping medical records*. MPS Casebook 13 (International), July 2000, 6-8

- 3.1.4 Be used for administrative or other purposes;
- 3.1.5 Be kept as direct evidence in litigation or for occupational disease or injury compensation purposes;
- 3.1.6 Be used as research data;
- 3.1.7 Be kept for historical purposes;
- 3.1.8 Promote good clinical and laboratory practices;
- 3.1.9 Make case reviews possible;
- 3.1.10 Serve as the basis for accreditation.⁴

4. COMPULSORY KEEPING OF RECORDS

- 4.1 Health care practitioners should enter and maintain at least the following information for each patient consulted:
 - 4.1.1 Personal (identifying) particulars of the patient.
 - 4.1.2 The bio-psychosocial history of the patient, including allergies and idiosyncrasies.
 - 4.1.3 The time, date and place of every consultation.
 - 4.1.4 The assessment of the patient's condition.
 - 4.1.5 The proposed clinical management of the patient.
 - 4.1.6 The medication and dosage prescribed.
 - 4.1.7 Details of referrals to specialists, if any.
 - 4.1.8 The patient's reaction to treatment or medication, including adverse effects.
 - 4.1.9 Test results.
 - 4.1.10 Imaging investigation results.
 - 4.1.11 Information on the times that the patient was booked off from work and the relevant reasons.
 - 4.1.12 Written proof of informed consent, where applicable.
- 4.2 Records should be kept in non-erasable ink and erasure fluid should not be used.

5. SIGNING OF OFFICIAL DOCUMENTS

Rule 15 of the HPCSA's ethical rules states that:

“Any student, intern or practitioner who, in the execution of his or her professional duties, signs official documents relating to patient care, such as prescriptions, certificates(excluding death certificates) patient records, hospital or other reports, shall do so by signing such document next to his or her initials and surname in block letters.”

⁴ Royal College of Pathologists, Marks and Spencer Publications Unit. *The retention and storage of pathological records and Archives, London, Royal College of Pathologists, 1995*

6. CERTIFICATES AND REPORTS

According to Rule 16 of the ethical guidelines:

“(1) A practitioner shall only grant a certificate of illness if such certificate contains the following information, namely -

- (a) the name, address and qualification of the practitioner;
- (b) the name of the patient;
- (c) the employment number of the patient (if applicable);
- (d) the date and time of the examination;
- (e) whether the certificate is being issued as a result of personal observations by the practitioner during an examination, or as the result of information received from the patient and which is based on acceptable medical grounds;
- (f) a description of the illness, disorder or malady in layman's terminology with the informed consent of the patient: Provided that if the patient is not prepared to give such consent, the medical practitioner or dentist shall merely specify that, in his or her opinion based on an examination of the patient, the patient is unfit to work;
- (g) whether the patient is totally indisposed for duty or whether the patient is able to perform less strenuous duties in the work situation;
- (h) the exact period of recommended sick leave;
- (i) the date of issuing the certificate of illness; and
- (j) a clear indication of the identity of the practitioner who issued the certificate which shall be personally and originally signed by him or her next to his or her initials and surname in printed or block letters.

(2) If preprinted stationery is used, a practitioner shall delete words which are irrelevant.

(3) A practitioner shall issue a brief factual report to a patient where such a patient, requires information concerning himself or herself.”

7. ISSUING OF PRESCRIPTIONS

On the issuing of prescriptions, Rule 17 states that:

“A practitioner -

- (a) shall be permitted to issue typewritten, computer-generated, pre-typed, pre-printed or standardised prescriptions for medicine scheduled in schedules I, II, III and IV of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), subject thereto that such prescriptions may only be issued under his or her personal and original signature;
- (b) shall issue handwritten prescriptions for medicine scheduled in schedules 5,6,7 and 8 above of the Act referred to in paragraph (a) under his or her

personal and original signature (see also rule 14).”

8. ALTERATION OF RECORDS

- 8.1 No information or entry may be removed from a health record.
- 8.2 An error or incorrect entry discovered in the record may be corrected by placing a line through it with ink and correcting it. The date of change must be entered and the correction must be signed in full. The original record must remain intact and fully legible.
- 8.3 Additional entries added at a later date must be dated and signed in full.
- 8.4 The reason for an amendment or error should also be specified on the record.

9. DURATION FOR THE RETENTION OF HEALTH RECORDS

- 9.1 Health records should be stored in a safe place and if they are in electronic format, safeguarded by passwords. Practitioners should satisfy themselves that they understand the HPCSA’s guidelines with regard to the retention of patient records on computer compact discs.
- 9.2 Health records should be stored for a period of not less than six (6) years as from the date they became dormant.
- 9.3 In the case of minors and those patients who are mentally incompetent, health care practitioners should keep the records for a longer period:
 - 9.3.1 For minors under the age of 18 years health records should be kept until the minor’s 21ST birthday because legally minors have up to three years after they reach the age of 18 years to bring a claim. This would apply equally for obstetric records.
 - 9.3.2 For mentally incompetent patients the records should be kept for the duration of the patient’s lifetime.
- 9.4 In terms of the Occupational Health and Safety Act (Act No. 85 of 1993) health records must be kept for a period of 20 years after treatment.
- 9.5 Notwithstanding the provisions in paras 9.3 and 9.4 above, the health records kept in a provincial hospital or clinic shall only be destroyed if such destruction is authorised by the Deputy Director-General concerned.
- 9.6 In addition to the time periods mentioned above there are a number of other factors that may require health records to be kept for longer periods, but no clear-cut rules exist in this regard. For instance, certain health conditions take a long period to manifest themselves, (e.g.asbestosis), and records of patients who may have been exposed to such conditions, should be kept for a sufficient period of time. The HPCSA recommends that this should not be less than 25 years.
- 9.7 A balance must be reached between the costs of (indefinite) retention of records (in terms of space, equipment, etc.) and the occasional case where the practitioners’ defence of a case of negligence is handicapped by the absence of records. The value of the record for academic or research purposes, and the risks resulting from the handling or complications of the case, are additional considerations.

- 9.8 Where there are statutory obligations that prescribe the period for which patient records should be kept, a practitioner must comply with these obligations.

10. OWNERSHIP OF RECORDS

- 10.1 In the case of state institutions, where records e.g radiographs are the property of the institution, original records and images should be retained by the institution. Copies must however, be made available to the patient (or referring practitioner) on request for which a reasonable fee may be charged in terms of the Promotion of Access to Information Act (Act No. 2 of 2000);
- 10.2 In cases where patients are required to pay for records and images (e.g. private patients or patients in private hospitals) such patients must be allowed to retain such records - unless the health care practitioners deem it necessary to retain such records for purpose of monitoring treatment for a given period. Should the patient however require the records and / or images to further or protect an interest (e.g. such as consulting with another practitioner) he or she must be allowed to obtain the originals for these purposes.
- 10.3 As the ownership of records in a multi-disciplinary practice depends on the legal structure of the practice, the governing body of such multi-disciplinary practice should ensure that these guidelines and the provisions of the Promotion of the Access to Information Act relating to health records are adhered to. The Act requires public institutions to appoint information officers to administer access to information, and similar provisions apply to private bodies.
- 10.4 Should a health care practitioner in private practice (both in a single practice and in a partnership) pass away, his or her estate, which includes the records, will be administered by the executor of the estate:
- 10.4.1 Should a practice be taken over by another health care practitioner, the executor shall carry over the records to the new health care professional. The new health care practitioner is obliged to take reasonable steps to inform all patients regarding the change in ownership and that the patient could remain with the new health care practitioner or could request that his or her records be transferred to another health care practitioner of his or her choice.
- 10.4.2 Should the practice not be taken over by another health care practitioner the executor should inform all patients in writing accordingly and transfer those records to other health care practitioners as requested by individual patients. The remaining files should be kept in safe keeping by the executor for a period of at least twelve (12) months with full authority to further deal with the files as he or she may deem appropriate - provided the provisions of the rules on professional confidentiality are observed.
- 10.4.3 It should be noted that certain partnership agreements may make specific provision for the management of a deceased partner's share in the partnership after the death of a partner and such management would include dealing with patient records.
- 10.5 If health care practitioners in private practice decide to close their practice for whatever reason they shall within three months of closure inform all their patients in writing that:
- 10.5.1 The practice is being closed as from a specific date;

- 10.5.2 Requests may be made that records are transferred to other health care practitioners of their choice;
- 10.5.3 After the date concerned, the records will be kept in safe-keeping for a period of at least twelve (12) months by an identified health care practitioner or health institution with full authority to deal with the files as he or she may deem appropriate, provided the provisions of the rules on professional confidentiality are observed.

11. ACCESS TO RECORDS

- 11.1 In terms of the law the following principles apply in regard to access to information in health records:
 - 11.1.1 A health care practitioner shall provide any person of age 12 years and older with a copy or abstract or direct access to his or her own records regarding medical treatment on request (Children's Act (Act No. 38 of 2005)).
 - 11.1.2 Where the patient is under the age of 16 years, the parent or legal guardian may make the application for access to the records, but such access should only be given on receipt of written authorization by the patient (Access to Information Act (Act No. 2 of 2000)).
 - 11.1.3 Information about termination of a pregnancy may not be divulged to any party, except the patient herself, regardless of the age of the patient (Choice on Termination of Pregnancy Act (Act No. 92 of 1996)).
 - 11.1.4 No health care practitioner shall make information available to any third party without the written authorisation of the patient or a court order or where non-disclosure of the information would represent a serious threat to public health (National Health Act (Act 61 of 2003)).
- 11.2 A health care practitioner may make available the records to a third party without the written authorisation of the patient or his or her legal representative under the following circumstances:
 - 11.2.1 Where a court orders the records to be handed to the third party;
 - 11.2.2 Where the third party is a health care practitioner who is being sued by a patient and needs access to the records to mount a defence.
 - 11.2.3 Where the third party is a health care practitioner who has had disciplinary proceedings instituted against him or her by the HPCSA and requires access to the records to defend himself or herself.
 - 11.2.4 Where the health care practitioner is under a statutory obligation to disclose certain medical facts, (e.g. reporting a case of suspected child abuse in terms of the Children's Act, (Act No. 38 of 2005)).
 - 11.2.5 Where the non-disclosure of the medical information about the patient would represent a serious threat to public health (National Health Act (Act No. 61 of 2003)).
- 11.3 In provincial hospitals medical records must be kept under the care and control of the clinical manager. Access to such records shall be subject to compliance with the

requirements of the Access to Information Act and such conditions as may be approved by the superintendent.

12. RETENTION OF PATIENT RECORDS ON CD-ROM

- 12.1 Storage of clinical records on computer compact disc (CD-ROM) is permissible, provided that protective measures are in place:
- 12.1.1 Only CD-ROM technology that is designed to record a CD once only, so that old information cannot be overwritten, but new information can be added is used;
 - 12.1.2 All clinical records stored on computer compact disc and copies thereof are to be encrypted and protected by a password in order to prevent unauthorised persons to have access to such information;
 - 12.1.3 A copy of the CD-ROM to be used in the practitioner's rooms will be in a read-only format;
 - 12.1.4 A back-up copy of the CD-ROM must be kept and stored in a physically different site in order that the two discs can be compared in the case of any suspicion of tampering;
 - 12.1.5 Effective safeguards against unauthorised use or retransmission of confidential patient information must be assured before such information was entered on the computer disc. The right of patients to privacy, security and confidentiality must be protected at all times.

13. CHECKLIST FOR HEALTH RECORD-KEEPING

Good notes imply good practice and the following checklist may serve to guide health care practitioners in the appropriate keeping of patient records:⁵

- 13.1 Records should be complete, but concise.
- 13.2 Records should be consistent.
- 13.3 Self-serving or disapproving comments should be avoided in patient records. Unsolicited comments should be avoided (i.e. the facts should be described, and conclusions only essential for patient care made).
- 13.4 A standardised format should be used (e.g. notes should contain in order the history, physical findings, investigations, diagnosis, treatment and outcome.).
- 13.5 If the record needs alteration in the interests of patient care, a line in ink should be put through the original entry so that it remains legible; the alterations should be signed in full and dated; and, when possible, a new note should refer to the correction without altering the initial entry.
- 13.6 Copies of records should only be released after receiving proper authorisation.
- 13.7 Billing records should be kept separate from patient care records.
- 13.8 Attached documents such as diagrams, laboratory results, photographs, charts, etc. should always be labelled. Sheets of paper should not be identified simply by being bound or stapled together – each individual sheet should be labelled.

⁵ Adapted from Torres, A, Proper S.: Medico-legal developments and the Dermatologist. *Advances in Dermatology*, Vol 12, 1987



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTHCARE PROFESSIONS**

**GENERAL ETHICAL GUIDELINES FOR
GOOD PRACTICE IN TELEMEDICINE**

**DEVELOPED BY THE HUMAN RIGHTS, ETHICS AND
PROFESSIONAL PRACTICE COMMITTEE**

Booklet No: 10

**PRETORIA
AUG 2014 [APPROVED BY COUNCIL]**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcsa@hpcsa.co.za

Website: <http://www.hpcsa.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, the practice of health care professions is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1. Introduction	3
2. Purpose	4
3. Definition of concepts	4
3.1. Telemedicine	4
3.2. Health Establishment	5
3.3 Healthcare Practitioner	5
3.4 The Consulting healthcare practitioner	5
3.5 The servicing healthcare practitioner	5
3.6 The Requesting patient	5
3.7 Other Terms relate to consultation	5
4. Ethical guidelines	6
4.1. Competence, registration and authorisation	6
4.2. Healthcare practitioner –patient relationship	7
4.3. Assumption of primary responsibility	7
4.4. Evaluation and treatment of patient	8
4.5 Professional duties	8
4.6. Duty to inform and informed consent	8
4.7 Patient confidentiality	10
4.8. Routine, specialists and emergency consultations	12
4.9. Quality, security and safety	13
5. Sources consulted	16

1. INTRODUCTION

1.1 The objective of the South African Telemedicine System as established by the National Department of Health is to deliver healthcare services at a distance to South African communities in under-served areas. The system has been established to alleviate the human resource crisis as experienced and is geared to improve the links and communication between developed healthcare facilities and the underdeveloped rural areas. Different categories of Health Care Practitioners will be involved.

1.2 The Health Professions Council of South Africa (HPCSA) has a mandate to regulate healthcare provision by ensuring that services are provided by qualified and skilled healthcare practitioners. This regulatory mandate applies to healthcare practitioner in both state and privately-owned health care institutions. It is the mandate of the HPCSA to protect the “patient” against possible abuse by healthcare practitioner on one hand and to provide guidance for good practice to the professions.

1.3 All Telemedicine services should involve a healthcare provider where there is an actual face-to-face consultation and physical examination of the patient in a clinical setting. The consulting practitioner will communicate the information to the servicing practitioner, who will then provide the necessary assistance.

Note: These guidelines must be read as a whole and not piece-meal as the overall purpose may be lost. The guidelines must further be read in conjunction with other ethical booklets of the HPCSA which include but are not limited to:

- Booklet No 1: General ethical guidelines for healthcare professions*
- Booklet No 9: Seeking patients’ informed consent*
- Booklet No 10: Confidentiality*

2. PURPOSE

The purpose of these guidelines is twofold:

- (a) Firstly to provide an ethical framework that draws from the core values and standards in Booklet No 1 and pertinent laws.
- (b) Secondly, to provide guidelines to Healthcare Practitioners engaged in telemedicine practices within and outside the South Africa.

3. DEFINITION OF CONCEPTS

These guidelines first provide definitions of telemedicine and other related terminology as used in the guidelines.

3.1 Telemedicine

For the purposes of these guidelines, “telemedicine” is defined as:

The practice of medicine using electronic communications, information technology or other electronic means between a healthcare practitioner in one location and a healthcare practitioner in another location for the purpose of facilitating, improving and enhancing clinical, educational and scientific healthcare and research, particularly to the under serviced areas in the Republic of South Africa.

Note:

1. Telemedicine involves secure videoconferencing or similar forms of technology which enable healthcare practitioners to replicate the interaction of traditional face-to-face consultations between healthcare practitioners and the patient.

2. Telemedicine as defined refers to where information is exchanged electronically either on or off-line, formally, informally or as a need for a second opinion.

3.2 Health establishment

“Health establishment” means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is designed to provide inpatient or outpatient treatment, and diagnostic or therapeutic interventions

3.3 Healthcare practitioner

“Healthcare practitioner” means a person providing health services, registered in terms of the Health Professions Act No 56 of 1974, to include any other appropriate disciplines as defined in the National Health Act No 61 of 2003.

3.4 The consulting healthcare practitioner

The “consulting healthcare practitioner” refers to the practitioner who conducts a “face-to-face” interview or examination with the patient or refers patient’s information to a remote location for further advice or intervention.

3.5 The servicing healthcare practitioner

The “servicing healthcare practitioner” refers to the practitioner who offers advice or intervention or patient information from a remote location.

3.6 The requesting patient

The “requesting patient” is the patient who requests to be treated by the servicing healthcare practitioner. This applies only where there is already an existing relationship between the patient and the healthcare practitioner.

3.7 Other terms that relate to consultation

Other terms relate to consultation as used in telemedicine as described by the World Medical Association:

- 3.7.1 Asynchronous: Refers to data transmission that involves a mechanism where the patient information from the consulting healthcare practitioner's site is temporarily stored and then retransmitted to the servicing healthcare practitioner's site or vice versa. A common asynchronous transmission includes the transmission of patient information via email.

- 3.7.2 Synchronous: Refers to the continuous, uninterrupted transmission of patient information from the consulting health care practitioner's site to the consultant health care practitioner's site, or vice versa. The flow of patient information does not include any storage or intended delay in the transmission of the patient data.

4. ETHICAL GUIDELINES

Although telemedicine has become an essential tool in alleviating human resource crises and supporting primary healthcare services, particularly those of vulnerable communities in South Africa. It also raises important ethical and legal issues.

4.1 Competence, registration and authorisation

- 4.1.1 According to the Health Professions Act, No 56 of 1974, registration is a prerequisite for practising a profession in terms of which a professional board has been established, where such practice is for gain within South Africa, or for any other health profession the scope which has been defined by the Minister in terms of the Act, unless a practitioner is registered in terms of the Act in respect of such profession.

- 4.1.2 Only practitioners who have been deemed competent and are registered in their respective professions are authorised to participate in telemedicine practice in

South Africa either as consulting healthcare practitioners or servicing healthcare practitioners.

- 4.1.3 In the case of telemedicine across country borders, practitioners serving South African patients should be registered with the regulating bodies in their original states as well as with the HPCSA.
- 4.1.4 Consulting healthcare practitioners are responsible for ensuring that the servicing healthcare practitioner is competent according to South African healthcare standards.
- 4.1.5 Consulting healthcare practitioners and servicing healthcare practitioners are held to the same standards of medical practice as healthcare practitioners who conduct face-to-face consultations.

4.2 Healthcare practitioner-patient relationship

- 4.2.1 The relationship between the patient and the healthcare practitioner is established when the practitioner agrees to treat the patient and the patient agrees to be treated.
- 4.2.2 In telemedicine the practice of medicine occurs where the patient is located at the time telemedicine technologies are used.
- 4.2.3 The relationship between the patient and the healthcare practitioner must be based on mutual trust and respect, and this applies to both servicing and consulting practitioners.
- 4.2.4 Core ethical values as outlined in the HPCSA guidelines for Healthcare practitioners are also applicable in telemedicine practice and the fact that a patient's information can be moved using electronic means does not alter the ethical duties of health care practitioner.

4.2.5 The professional discretion of healthcare practitioners engaging in telemedicine regarding the diagnosis, scope of care or treatment should not be limited or influenced by non-clinical considerations of telemedicine technologies.

4.3 Assumption of primary responsibility

4.3.1 The World Medical Association (WMA) makes a distinction between telemedicine consulting and the servicing practitioners regarding where the primary responsibility lies.

4.3.2 According to the WMA:

(a) The consulting practitioner remains responsible for the treatment, decisions and other recommendations given to the patient, as well as for keeping detailed records of the patient's condition and information transmitted and received from the servicing practitioner.

(b) The servicing practitioner must keep detailed records of the advice he or she delivers as well as the information he or she receives and on which the advice is based.

(c) The servicing practitioner must further ensure that the advice or treatment suggestions given were understood by the consulting practitioner or the patient.

4.4 Evaluation and treatment of patient

4.4.1 A documented medical evaluation must be done and the relevant clinical history necessary to diagnose underlying conditions as well as any contra-indications regarding the recommended treatment must be obtained before providing treatment, including issuing prescriptions, electronically or otherwise.

4.4.2 Treatment, including issuing a prescription based solely on an online questionnaire does not constitute an acceptable standard of care.

4.4.3 When prescribing care using telemedicine consulting practitioners should ensure that informed consent is taken in accordance with the standards practice used in face-to-face issuing of prescriptions.

4.5 Professional duties

4.5.1 Healthcare practitioners engaging in telemedicine must observe the professional duties imposed in the HPCSA's General Ethical Guidelines for Good Practice.

4.5.2 Duties to patients include, but are not limited to, always acting in the best interest or well-being of the patient, respecting patients' privacy and dignity, giving patients the information they need about their conditions, and maintaining confidentiality at all times as required by the National Health Act No 61 of 2003 and the SA National Patients' Rights Charter.

4.5.3 Healthcare practitioners should not give medical advice or provide treatment using telemedicine without obtaining proper informed consent from the patient for both the treatment to be given and the use of telemedicine technology.

4.5.4 The consulting and servicing healthcare practitioners they should verify:

- (a) The location of the consulting or servicing healthcare practitioner;
- (b) The identity and qualifications of the consulting or servicing healthcare practitioner; and
- (c) The identity of the patient.

4.6 Duty to inform and informed consent

4.6.1 This section must be read in conjunction with HPCSA guidelines regarding informed consent in Booklet 9 and the provisions of the National Health Act.

4.6.2 Informed consent for the use of telemedicine technologies must be obtained in writing.

4.6.3 Informed consent documentation for telemedicine practice should include the following:

- (a) The identities of the patient and the servicing healthcare practitioner.
- (b) The servicing healthcare practitioner's practice number.
- (c) The types of transmissions consented to using telemedicine technologies (e.g. prescriptions, refills, appointment scheduling, patient education etc.).
- (d) Agreement by the patient that the servicing practitioner will decide whether or not the condition being diagnosed or treated is appropriate for a telemedicine consultation.
- (e) Details of the security measures taken with the use of telemedicine technologies, such as encrypting data, password protected screen savers and data files, or the use of other reliable authentication techniques.
- (f) Any material risks to confidentiality arising from the use of telemedicine technologies that may influence the patient's decision to consent.
- (g) The patient's express consent to the transmission of the patient's personal medical information to a consulting healthcare practitioner or other appropriate third parties.

4.6.3 When telemedicine is used the patient should be informed regarding who will access their information, the purpose of the telemedicine service, the cost of the service and what the implications of the use of such information will be.

4.6.4 It is the duty and responsibility of the consulting practitioner to obtain informed consent for telemedicine purposes.

4.6.5 The documentation regarding informed consent for telemedicine practice should include the following:

- (a) The patient's name and address and the location or site of consultation;
- (b) The consulting practitioner's name, practice address and number, and location;
- (c) The servicing practitioner's or practitioner's names, practice addresses and numbers, and location;
- (d) A brief explanation of telemedicine;
- (e) The types of transmissions consented to using telemedicine technologies (e.g. prescriptions, refills, appointment scheduling, patient education etc.).
- (f) Details of the security measures taken with the use of telemedicine technologies, such as encrypting data, password protected screen savers and data files, or the use of other reliable authentication techniques.
- (g) Any material risks to confidentiality arising from the use of telemedicine technologies that may influence the patient's decision to consent.
- (h) The expected risks, possible benefits of and alternatives to telemedicine;
- (i) Agreement by the patient that the servicing practitioner will decide whether or not the condition being diagnosed or treated is appropriate for a telemedicine consultation.
- (j) The patient's agreement, after a full explanation was given, including the patient's express consent to the transmission of the patient's personal medical information to a consulting healthcare practitioner or other appropriate third parties.
- (k) The signature of patient, the patient's parent, the patient's guardian or the patient's caregiver - the relationship to the patient should be specified;
- (l) The signature of the witness.

- 4.6.6 A copy of the consent form should be kept with patient's records and a duplicate given to the patient.
- 4.6.7 In the case of videoconference consultations, the patient must be aware of the presence of other people on the other side, and that the patient's identity may be revealed to such people, and must consent to this.

4.7 Patient confidentiality

- 4.7.1 The patient must at all times be assured that their confidentiality is protected.
- 4.7.2 Patient confidentiality should be ensured at both the consulting and servicing practitioners' sites and should follow the provisions of the Constitution, the National Health Act No 61 of 2003, the Promotion of Access to Information Act No 2 of 2000, the Protection of Personal Information Act No 4 of 2013, the Common law and the HPCSA's ethical guidelines on patient confidentiality in Booklet 10 which generally state that it is every practitioner's duty to make sure that information is effectively protected against improper disclosure at all times.
- 4.7.3 HPCSA's booklet on Confidentiality further provides guidelines on how patient information may be disclosed for example, in the case of research, education, clinical audit, financial audit or even for the publication of case histories and photographs].
- 4.7.4 Policies and procedures for documentation, maintenance and transmission of records regarding telemedicine consultations should be maintained at the same standard of care as face-to-face consultations.
- 4.7.5 Policies and procedures for telemedicine should deal with: (a) Confidentiality; (b) Healthcare personnel apart from the healthcare practitioners who will process the electronic information; (c) Hours of operation; (d) Types of transactions that are permitted electronically; (e) Required patient information to be included in electronic communications (e.g. name, identification number and type of transaction); (f) Archival and retrieval oversight mechanisms; and (g) Quality oversight mechanisms.

- 4.7.6 Electronic transmissions, (e.g. email, prescriptions and laboratory results) must be secure within existing technology (e.g. password protected, encrypted electronic prescriptions or other reliable authentication techniques). It is the responsibility of the healthcare practitioners to ensure that these non-healthcare personnel do not violate patient confidentiality.
- 4.7.7 All patient-practitioner electronic communications must be stored and filed in the patient's medical record file in line with traditional record-keeping policies and procedures.

4.8 Routine, specialists and emergency consultations

There is a need to provide guidelines on routine, emergency or specialist consultations using telemedicine technologies.

4.8.1 Routine telemedicine

- (a) Patient-initiated or second opinion telemedicine should be restricted to situations in which a previously existing healthcare-patient relationship enables the healthcare practitioner to gather sufficient knowledge of the patient's clinical condition to be able to render a proper and clinically justifiable diagnosis, treatment or recommendation.
- (b) This recommendation is in line with the WMA's regulations that telemedicine is only used as an adjunct to normal medical practice, and only replaces face-to-face services where the quality and safety of patient care is not compromised and the best available resources are used in securing and transmitting patient information.

4.8.2 Specialist telemedicine

- (a) Specialist telemedicine consultations form the bulk of telemedicine practice in South Africa because of human resource capacity challenges – particularly in rural areas.
- (b) These challenges do not however mean that patients should be over- or under-served.
- (c) The ethical guidelines for good practice as well as the ethical rules of conduct for practitioners registered with the HPCSA should be taken into consideration at all times.

4.8.3 Emergency telemedicine

- (a) Emergency telemedicine involves judgements by the healthcare practitioner often based on sub-optimal patient information.
- (b) In emergencies, the health and wellbeing of the patient are the determining factors with regard to stabilising the patient and having the patient referred for thorough medical care.
- (c) The practitioner must provide the patient with emergency instructions when the care provided by telemedicine indicates that a referral to an acute care or emergency facility is necessary for the immediate treatment of the patient.
- (d) The emergency instructions should be in writing and appropriate to the services being rendered via telemedicine.

4.9 Quality, security and safety of patient information and records

Rules on confidentiality and security of patient information applies to telemedicine as well, especially with regard to transmission and storage.

- 4.9.1 Every registered healthcare practitioner engaging in telemedicine practices takes responsibility for the quality of service delivered as well as confidentiality, security and safety of patients' information.

4.9.2 Patient information and records should consist of copies of all patient-related electronic communications, including:

- (a) Patient-practitioners communications;
- (b) Prescriptions;
- (c) Laboratory and test results;
- (d) Evaluations and consultations;
- (e) Records of past care;
- (f) Instructions obtained or produced in connection telemedicine technologies;
and
- (g) Signed informed consents to treatment and use of telemedicine.

4.9.3 The patient's records established during the use of telemedicine must be accessible and documented for both the healthcare practitioners involved and their patients.

4.9.4 It is the registered healthcare practitioner's responsibility to ensure that non-registered personnel who may be offering auxiliary or technical services, are aware of the need for such quality, security and safety and that they adhere to the stipulated guidelines.

4.9.5 Quality assurance

- (a) Healthcare practitioners, both from the consulting and servicing sites, should not practice telemedicine without ensuring that the equipment and accessories used are optimally operational.
- (b) Periodical quality control tests and servicing of equipment should be carried out and records kept for verification.
- (c) The quality and quantity of patient information received should be sufficient and relevant for the patient's clinical condition in order to ensure that accurate medical decisions and recommendations are made for the benefit of the patient.
- (d) Good communication contributes to quality patient information being transmitted from one practitioner to the other.

- (e) Quality should further be ascertained in the manner of documenting patient information.
- (f) A standardised manner of documentation is recommended to ensure that all healthcare practitioners adhere to the same protocol in terms of history taking, reporting on findings, creation of reserves and hard copies where necessary.
- (g) Where images are transmitted from one location to the other, it is the responsibility of both the consulting and servicing practitioner to ensure that there is no critical loss of image resolution from acquisition to final display.

4.9.6 Security

- (a) Patient information should only be transmitted from one site to the other and stored, with the full knowledge and approval of the patient, in line with the informed consent guidelines.
- (b) Only the information that is relevant to the clinical history of the patient should be transmitted electronically.
- (c) To protect the identity of the patient when information is transmitted between sites, it is essential that personal identification should be removed and the transmitted information is encrypted.
- (d) All personal computers of the telemedicine service should be accessed by authorised personnel only through the use of a login password.
- (e) There are three factors central to the security of patient information, namely:
 - i) Privacy: Who can access it?
 - ii) Authenticity: Who sends the information?
 - iii) Integrity: Has the information been altered during its transmission through the public networks?
- (f) Access to information by other healthcare practitioner, patients or third party should be authorised by the healthcare provider in charge of the patient and be carried out according to the rules and regulations as outlined in the Promotion of Access to Information Act, of 2000.

4.9.7 Safety

Health care practitioners using telemedicine should:

- (a) Avoid accidental damage and loss of patient information;
- (b) Provide safe procedures to avoid any alteration or elimination of patient data;
- (c) Ensure that patient information obtained electronically is kept in line with the HPCSA's guidelines on the keeping of patients' records in Booklet 15;
- (d) Comply with the legal requirements for data messages in the Electronic Communications and Transactions Act No 25 of 2002 regarding the protection of information and the principles regarding the electronic collection of personal information.

5. SOURCES CONSULTED

1. Department of Health. **A Telemedicine Strategy for South Africa. 2010 – 2015 Extending Better Healthcare.** *Version 3*
2. Federation of State Medical Boards. Policy Guidelines for the Safe Practice of Telemedicine. 2014. Available from www.fsmb.org/pdf/FSMB_Telemedicine_Policy.pdf 29 April 2014.
3. World Health Organisation. Telemedicine. Opportunities and developments in Member States. Report on the Second Global Survey on eHealth. Global Observatory for eHealth Series. 2010. Vol 2. Available from: http://www.who.int/goe/publications/goe_telemedicine_2010.pdf Accessed on 06/02/2013.
4. World Medical Association. **Ethics Unit. What's New?** Available from: http://www.wma.net/e/ethics/whats_new.htm Accessed on 02/01/2008, Issued November 2007.
5. HPCSA Act No 56 of 1974 and related Guidelines Booklets.
6. Ontario Association of Radiologists. 2007. New OAR Teleradiology Standard Approved. OAR board approves new teleradiology standard. Available from: <http://www.oar.info/pdf/NewOARTeleradiologyStandards.pdf> Accessed on 04/01/2008
7. Telemedicine Information Exchange. **Informed consent and Evaluation forms.** March 9, 2007. Available from: http://www.tie.telemed.org/telemed101/policy_forms_links.asp Accessed on 03/02/2008
8. White, P. Legal Issues in Teleradiology- distant thoughts. **British Journal of Radiology.** 75 (2002), 201-206.
9. Kekana M, Noe P & Mkhize B. **The Practice of telemedicine and challenges to the Regulatory Authorities.** December 2010. SAJBL. Vol 3. No 1.
10. Mars M & Jack C. **Why Telemedicine is a challenge to the Regulators.** December 2010. SAJBL. Vol 3.No 2.



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

GUIDELINES FOR GOOD PRACTICE IN THE HEALTH CARE PROFESSIONS

GUIDELINES ON OVERSERVICING, PERVERSE INCENTIVES AND RELATED MATTERS

BOOKLET 11

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcsa@hpcsa.co.za

Website: <http://www.hpcsa.co.za>

THE SPIRIT OF PROFESSIONAL POLICY GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practice as a health care professional is a moral enterprise. In this spirit the HPCSA presents the following ethical policy guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1	INTRODUCTION.....	2
2	DEFINING OF CONCEPTS	3
3	OVERSERVICING, PERVERSE INCENTIVES AND RELATED MATTERS	6
3.1	OVERSERVICING RULE 7.....	6
3.2	MANUFACTURING RULE 23.....	6
3.3	ADVERTISING RULE 3	7
3.4	PREFERENTIAL USAGE OR PRESCRIPTIONS RULE 23.....	7
3.5	REFERRALS RULE 24.....	7
3.6	TECHNOLOGICAL EQUIPMENT	7
3.7	FINANCIAL INTEREST IN HOSPITALS RULE 23A.....	<u>78</u>
3.8	RENTALS AS PERVERSE INCENTIVES	8
3.9	COMMISSION RULE 7	8
3.10	CHARGING OR RECEIVING FEES RULE 7	9
3.11	SHARING OF FEES	9
3.12	CONTRACTS.....	9
3.13	CONTINUING PROFESSIONAL DEVELOPMENT.....	9

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".² To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, the practice of health care professions is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

² Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

GUIDELINES REGARDING OVER SERVICING, PERVERSE INCENTIVES AND RELATED MATTERS CONCERNING HEALTH CARE PROFESSIONALS

APPLICABLE TO ALL HEALTH CARE PROFESSIONALS

PREAMBLE

WHEREAS SECTION 49(1) of the Health Professions Act, 1974 (Act No. 56 of 1974) (“the Act”) provides that the council shall, in consultation with a professional board, from time to time make rules specifying the acts or omissions in respect of which the professional board may take disciplinary steps under this Chapter: Provided that the powers of a professional board to inquire into and deal with any complaint, charge or allegation relating to a health profession under this Chapter, shall not be limited to the acts or omissions so specified;

AND WHEREAS council has made the rules in terms of section 49(1) of the Act;

NOW THEREFORE the HPCSA issues the following guidelines in respect of some of the above rules:

1 INTRODUCTION

- 1.1 The Health Professions Council of South Africa (HPCSA) requires that health care practitioners should at all times act in the best interests of their patients and regard the clinical needs of their patients as paramount. To this end, a health care practitioner should always try to avoid potential conflicts of interest and maintain professional autonomy, independence and a commitment to the relevant professional and ethical rules and policies applicable. Any conflicts of interest, incentives or forms of inducement that threaten such autonomy, independence or commitment to the appropriate professional and ethical rules and policies or that do not accord first priority to the clinical needs of patients, are unacceptable. The ownership and use of high technology equipment creates a special problem, not only because of its inappropriate use by health care practitioners who are not properly qualified, but also due to overservicing by appropriately qualified health care professionals. In general these guidelines cover the problems related to the use of high technology equipment. In particular, it needs to be emphasised, that over servicing of any kind is unacceptable.
- 1.2 In these guidelines, the HPCSA seeks to identify incentive schemes and forms of inducement that it finds unacceptable. It must be clearly stated that the perverse incentives or potential conflicts of interest set out in this document should not in any way be regarded as an exhaustive list. The principles underlying these listed perverse incentives apply in every case of alleged unprofessional conduct on the part of a health care practitioner, and where breached will lead to an investigation by an appropriate health care authority or the HPCSA.
- 1.3 These guidelines regarding over servicing, perverse incentives and related matters shall be applicable to health care practitioners in both the public and private sectors.
- 1.4 It should further be noted that in terms of these guidelines, it is an offence either to offer a perverse incentive or to accept one.

- 1.5 In addition to any action that the HPCSA may take in terms of other legislation that governs the health professions, the HPCSA may, at its own discretion and where it believes such action is warranted, lay a charge against any person, or corporate body or other legal entity in terms of the Prevention and Combating of Corrupt Activities Act, 2004 (Act No. 12 of 2004), should the actions or omissions of such person, body or other legal entity be in breach of the provisions of that Act.

2 DEFINING OF CONCEPTS

For the purpose of these guidelines, the following concepts will have the meanings described below, unless the context indicates otherwise. It should be noted that these concepts have not been defined for legal purposes, but merely to clarify the meaning of the guidelines. It should further be noted that some of these definitions have been based on those in certain Acts of Parliament in the Medicine and Substance Related Act, 1965 (Act No. 101 of 1965)

- 2.1 “Advertise” in relation to any health establishment or orthodox medicine, complementary medicine, veterinary medicine, medical device or scheduled substance or health related product or health related service, means any written, pictorial, visual or other descriptive matter or verbal statement or reference in respect thereof:

2.1.1 Appearing in any newspaper, magazine, pamphlet or other publication; or

2.1.2 Distributed to members of the public; or

2.1.3 Brought to the notice of members of the public in any manner whatsoever,

That is intended to promote the sale of that orthodox medicine, complementary medicine, veterinary medicine, medical device or scheduled substance or health related product or to attract patients to any particular health establishment or health related service.

- 2.2 “Complementary medicine” means any substance, or mixture of substance, which:

2.2.1 Originates from a plant, mineral or animal, and which may be, but is not limited to being classified as herbal, homeopathic, ayurvedic or nutritional; and

2.2.2 Is used or intended to be used for, or manufactured or sold for use in, or purported to be useful in, complementing the healing power of a human or animal body or for which there is a claim regarding its effect in complementing the healing power of a human or animal body in the treatment, modification, alleviation or prevention of a disease, abnormal physical or mental state or the symptoms thereof in a human being or animal; and

2.2.3 Is used in, but not limited to, the disciplines of Western herbal, African traditional, traditional Chinese, Homeopathy, Ayurveda, Unani, Antroposophy, Aromatherapy and Nutritional supplementation; or

2.2.4 Because of its origin, intended use or use in a discipline, is determined by the Authority, by notice in the Gazette, to be a complementary medicine.

- 2.3 “Device” see definition of “Medical device”.

- 2.4 “Dual Practice” means a situation where a practitioner combines clinical practice in the public service with a clinical practice in the private sector. For practitioners employed in the Public Service, the equivalent of Dual Practice is referred to as Remunerative Work Outside Public Service (RWOPS). For practitioners in Private practice this refers to a

situation where a practitioner is employed in the public service either on sessional or part time basis.

- 2.4 “**Endorse**” means any action whereby a person or body attaches approval to or sanctions any health establishment or orthodox medicine, complementary medicine, veterinary medicine, medical device or scheduled substance or other health related product or health related service with a view to encouraging or promoting the preferential use or preferential sale thereof for the purpose of financial gain or other valuable consideration.
- 2.5 “Health care professional” means any person registered in terms of the applicable Act which governs the functioning of any of the Councils that form part of the Forum of Statutory Health Councils. This includes persons registered by the Health Professions Council of South Africa. The term also includes registered student health care practitioners.
- 2.6 “Health care practitioner” means any person registered with the HPCSA.
- 2.7 “Health establishment” means an institution, facility, building or place where persons receive treatment, diagnostic or therapeutic interventions or other allopathic or complementing health services and it includes facilities such as a clinic, mobile clinic, hospital, community health centre, maternity home or unattached delivery suite, convalescent home, consulting room, dispensary of health related treatment or aids and appliances, first aid station, orthopaedic workshop, dental laboratory or workshop, ambulance, unattached operating theatre, sanatorium, laboratory, pharmacy, occupational health clinic, radiological clinic, and health spa or hydro.
- 2.8 “Health related product” means any commodity other than orthodox medicine, complementary medicine, veterinary medicine, medical device or scheduled substance which is produced by human effort or some mechanical, chemical, electrical or other human engineered process for medicinal purposes or other preventive, curative, therapeutic or diagnostic purposes in connection with human health.
- 2.9 “Improper financial gain or other valuable consideration” means money, or any other form of compensation, payment, reward or benefit which is not legally due or which is given on the understanding, whether express, implied or tacit, that the recipient will engage or refrain from engaging in certain behaviour in a manner which is either:
- 2.9.1 Illegal; and/or
 - 2.9.2 Contrary to ethical or professional rules; and/or
 - 2.9.3 Which, in the opinion of a the HPCSA, may adversely affect the interests of a patient or group of patients,
- In order to procure some direct or indirect advantage, benefit, reward or payment for the person offering or giving the said money, compensation, payment, reward or benefit, and “perverse incentive” has the same meaning.
- 2.10 “Medicinal purposes” in relation to a scheduled substance, means the purpose of treatment or prevention of a disease or some other definite curative or therapeutic purpose, but does not include the satisfaction or relief of a habit or a craving for the substance used or for any other scheduled substance, except where the substance is administered or used in a hospital or similar institution maintained wholly or partly by the Government or a provincial administration, or approved for that purpose by the Minister of Health.

- 2.11 “Medicine” means any substance or mixture of substances intended to be used by, or administered to human beings, for any of the following therapeutic purposes, namely:
- 2.11.1 Treating, preventing or alleviating symptoms of disease, abnormal physical or mental state or the symptoms thereof;
 - 2.11.2 Diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
 - 2.11.3 Otherwise preventing or interfering with the normal operation of physiological function, whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of that function.

And “orthodox medicine” has the same meaning.

- 2.12 “Medical device” means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent or any other article, whether used alone or in combination, including software necessary for its proper application used for or purporting to be suitable for use or manufactured or sold for use in or on a human or animal body:
- 2.12.1 In the diagnosis, prevention, monitoring, treatment or alleviation of disease; or
 - 2.12.2 In diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; or
 - 2.12.3 In investigation, replacement or modification of the anatomy or of a physiological process; or
 - 2.12.4 In the diagnosis of pregnancy, or the control of conception or termination of pregnancy,

And which does not achieve its principal intended action in or on the human body by chemical, pharmacological, immunological or metabolic means, but which may be assisted in its function by such means: and “**device**” has the same meaning.

- 2.13 “Orthodox medicine” see definition of “Medicine”.
- 2.14 “Overservicing” means the supply, provision, administration, use or prescription of any treatment or care (including diagnostic and other testing, medicines and medical devices) which is medically and clinically not indicated, unnecessary or inappropriate under the circumstances or which is not in accordance with the recognised treatment protocols and procedures, without due regard to both the financial and health interests of the patient.
- 2.15 “Perverse incentive” see definition of “improper financial gain or other valuable consideration”.
- 2.16 “Promote” means any action taken by a person or body or allowed to be taken by such person or body to further or to encourage the preferential use of any health establishment or orthodox medicine, complementary medicine, veterinary medicine, medical device or scheduled substance or health related product or health related service or to further or to encourage the preferential sale of any such product or service for the purpose of financial gain or other valuable consideration: This definition does, however, not prohibit the practice of those professions where, in terms of their scopes of practice, it is appropriate to sell such product or service at market related prices.

- 2.17 “Scheduled substance” means any medicine or other substance prescribed by the Minister under [section 22A](#); of the Medicines and Related Substances Act (Act No. 101 of 1965).
- 2.18 “Spouse” means a person’s partner in marriage and includes for the purpose of this policy statement, a person with whom another person lives as if they were married or with whom one habitually cohabits.
- 2.19 “Trade” means an act or instance of buying, selling or purchasing goods and services for the purpose of financial gain or other valuable consideration.
- 2.20 “Veterinary medicine” means any substance or mixture of substances intended or manufactured for use in connection with animals for diagnosis, treatment, alleviation, modification or prevention of disease or unhealthy physical conditions, for the improvement of growth, production or working capacity, for the lasting capacity of carcasses, for curing, correcting or modifying behaviour or for humane euthanasia, but does not include foodstuffs.

3 OVERSERVICING, PERVERSE INCENTIVES AND RELATED MATTERS

The following acts or omissions are not permissible for any health care practitioner, nor is it ethical for any health related body to encourage health care professionals to engage in any of them:

3.1 OVERSERVICING RULE 7

Health care practitioners shall not:

- 3.1.1 Provide a service or perform or direct certain procedures to be performed on a patient that are neither indicated nor scientific or have been shown to be ineffective, harmful or inappropriate through evidence-based review.
- 3.1.2 Refer a patient to another health care practitioner for a service or a procedure that is neither indicated nor scientific or has been shown to be ineffective, harmful or inappropriate through evidence-based review.

[Note: Over servicing by ordering or providing more tests, procedures or care than is strictly necessary, is a common problem in modern medicine. Health care practitioners must therefore not engage in any act that would constitute over servicing of patients].

3.2 MANUFACTURING RULE 23

Health care practitioners shall not manufacture or participate in the manufacture, for commercial purposes or trade, of orthodox medicine, complementary medicine, veterinary medicine, a medical device or a scheduled substance or a health related product, except where such medicine or device or substance or product forms an integral part of the normal scope of practice of the health care practitioner concerned and where explicit permission was granted to a health care professional by the HPCSA to manufacture or to participate in the manufacture of such medicine, device, substance or product.

3.3 ADVERTISING RULE 3

Health care practitioners shall not advertise or endorse or encourage the use of any health establishment or orthodox medicine, complementary medicine, veterinary medicine, medical device or scheduled substance or health related product or health related service in a manner that unfairly promotes the practice of a particular health care practitioner or a health care facility for the purpose of financial gain or other valuable consideration.

3.4 PREFERENTIAL USAGE OR PRESCRIPTIONS RULE 23

Health care practitioners shall not engage in or advocate the preferential use of any health establishment or medical device or health related service or prescribe any orthodox medicine, complementary medicine, veterinary medicine or scheduled substance, if any financial gain or other valuable consideration is derived from such preferential usage or prescription or the advocacy of preferential usage by the health care professional.

3.5 REFERRALS RULE 24

3.5.1 Self-referrals

Health care practitioners may only refer their clients or patients to any health establishment in which such health care practitioner or a close family member or business associate has a financial interest or a potential conflict of interest if such interest has been declared to and approved by the HPCSA and on condition that such interest is discussed and agreement reached with the patient prior to the referral for the patient's consent.

3.5.2 Other referrals

Health care practitioners shall not refer their clients or patients to any health establishment or to any other health care professionals if such referral would constitute overservicing.

3.5.3 Practitioners must not consult with one patient in more than one capacity.

3.6 TECHNOLOGICAL EQUIPMENT

3.6.1 Health care practitioners shall only own and use technological equipment if it forms an integral part of their scope of the profession and practice and on condition that the health care practitioner concerned has received appropriate training in using and managing such equipment.

3.6.2 Health care practitioners shall not over-use equipment for procedures, tests and other applications that are not indicated, scientific or based on evidence. This constitutes overservicing and is prohibited.

3.6.3 Health care professionals shall not use technological equipment, health care products or devices for profiteering and must refrain from charging patients fees for the use of such products or devices that are not market related.

3.7 FINANCIAL INTEREST IN HOSPITALS RULE 23A

A practitioner may have a direct or indirect financial interest or shares in a hospital or any other health care institution: Provided that -

- (a) such interests or shares are purchased at market-related prices in arm's length transactions;
- (b) the purchase transaction or ownership of such interest or shares does not impose conditions or terms upon the practitioner that will detract from the good, ethical and safe practice of his or her profession;
- (c) the returns on investment or payment of dividends is not based on patient admissions or meeting particular targets in terms of servicing patients;
- (d) such practitioner does not over-service patients and to this end establishes appropriate peer review and clinical governance procedures for the treatment and servicing of his or her patients at such hospital or health care institution;
- (e) such practitioner does not participate in the advertising or promotion of the hospital or health care institution, or in any other activity that amounts to such advertising or promotion;
- (f) such practitioner does not engage in or advocate the preferential use of such hospital or health care institution;
- (g) the purchase agreement is approved by the council based on the criteria listed in paragraphs (a) to (f) above; and
- (h) such practitioner annually submit a report to the council indicating the number of patients referred by him or her or his or her associates or partners to such hospital or health care institution and the number of patients referred to other hospitals in which he or she or his or her associates or partners hold no shares.

3.8 RENTALS AS PERVERSE INCENTIVES

Health care practitioners shall not:

- 3.8.1 Pay rentals in lease agreements between health care practitioners and health establishments that are not market related or are at preferential rates.
- 3.8.2 Enter into lease agreements with health establishments or services that wish to rent their consulting rooms at rates conditional on the health care practitioner achieving a certain turnover or targets such as admission of a specific number of patients at a private health care facility.
- 3.8.3 Rent consulting rooms from health establishments or services under financial arrangements that are not openly available to other similarly qualified health care practitioners.

3.9 COMMISSION RULE 7

3.9.1 Accepting commission

Health care practitioners shall not accept commission or any financial gain or other valuable consideration from any person or body or service in return for the purchase, sale or supply of any goods, substances or materials used by the health care professional in his or her practice.

3.9.2 Paying commission

Health care practitioners shall not pay commission or render any financial gain or other valuable consideration to any person for recommending patients.

3.10 CHARGING OR RECEIVING FEES RULE 7

3.10.1 For referring patients

Health care practitioners shall not charge a fee or receive any financial gain or other valuable consideration for referring patients to the other health professional or for participation in drug trials or other research trials of a similar nature.

3.10.2 For seeing representatives

Health care practitioners shall not charge a fee or receive any financial gain or other valuable consideration for seeing medical representatives

3.10.3 For services not personally rendered

Health care practitioners shall not charge or receive fees for services not personally rendered by either a health care professional himself or herself or by an unregistered person in his or her employ, except for services rendered by another health care practitioner or person registered in terms of the Health Professions Act (Act No. 56 of 1974), that regulates the particular profession, with whom the health care practitioner is associated as a partner, shareholder or *locum tenens*.

3.10.4 Charging consultation fee for an appointment that was not honoured (Rule 7)

A practitioner shall not charge or receive fees for services not rendered. An appointment that was not honoured by the patient is equivalent to services not rendered, and for that, a practitioner may not charge or receive fees

3.11 SHARING OF FEES

Health care practitioners shall not share fees with any person or health care professional who has not taken a commensurate part in the service for which the fees are charged.

3.12 CONTRACTS

3.12.1 Health care practitioners shall not enter into a contract to work in a particular health establishment or service on the understanding that the health care professional generates a particular amount of revenue for such health establishment or service.

[Note: A health establishment or service that equips a theatre, ward or other facility for a specific health care practitioner according to his or her specifications may enter into a contractual agreement with such health care professional on condition that such health establishment or service may not stipulate any turnover targets for the health care practitioner concerned].

3.13 CONTINUING PROFESSIONAL DEVELOPMENT

With regard to continuing professional development (CPD), the HPCSA wishes to state the following:

3.13.1 Collaborative efforts

Historically there has been a close collaboration between health care practitioners and the pharmaceutical and health supply industry that extended particularly to CPD. Health care is to a large extent self-governing and practitioners must ensure that their participation in such collaborative efforts is in keeping with their ethical duties towards patients and society.

3.13.2 Educational needs of targeted group

Continuing professional development activities should address the educational needs of the targeted health care group.

3.13.3 Health care provider organisations

The decision on content and choice of continuing professional development activities, as well as funding arrangements lies ultimately with the health care provider organisations such as professional associations, their branches and groups who should not be in a position of conflict of interest by virtue of any relationship with the funding body. The organisers may acknowledge financial or other aid received, but should not identify any specific products. Generic names of products should be used rather than trade names in the course of continuing professional development activities.

3.13.4 Funding

Funds for continuing professional development activities should preferably be in the form of an educational grant payable to the health care provider organisation arranging the activity.

3.13.5 Travel, lodging and other expenses with regard to the attendance of CPD events

No travel or lodging costs or other expenses should be paid by the industry directly to the individual health care practitioners to attend a CPD event. However indirect funding or scholarship of CPD events may be permissible in instances where, such sponsorships are paid to the organisers of the CPD events who in turn will identify, through a transparent selection process, deserving candidates based on such factors as historically disadvantaged individuals status, gender, geographical location in terms of rural and inaccessible locations, young practitioners and developing practitioners etc. The organisers may extend reasonable honoraria and imbursement for travel, lodging and meal expenses to speakers. The principal event should at all times centre around education and not around meals, entertainment or other hospitality, the cost of which should not exceed that level at which the recipients might reasonably be expected to incur for themselves under similar circumstances.

3.13.6 Travel, lodging and other expenses with regard to the attendance of international conferences

3.13.6.1 It is a well established practice and an acknowledged fact that health care practitioners and educators should be exposed to new knowledge and insights into their respective professions and disciplines by attendance at international conferences, either locally or overseas. It is, however, also of the utmost importance that young and upcoming health care practitioners and educators and those from disadvantaged backgrounds be given an equal opportunity to expand their knowledge and understanding with regard to their respective professions and disciplines by attendance at international conferences.

3.13.6.2 It will, therefore, be permissible for companies to sponsor delegates to attend international conferences, either directly or through professional associations or societies, with the proviso that a fair and transparent process should be followed in the election and sponsoring of delegates to attend such events, especially with regard to the attendance of such conferences by young and upcoming health care professionals and educators and those from disadvantaged backgrounds.

3.13.6.3 Sponsorships should be earmarked for specific educational events and conferences and not for holiday purposes.

3.13.7 Distinction between education, training and product promotion

A distinction should be made between education and training on the one hand and product promotion on the other. Health care practitioners cannot earn CEUs for attending product launches or other product promotion events. No travel, lodging or other expenses of health care practitioners should be paid for attendance at product promotion events or product launches. However, modest meals may be provided.

3.14	Dual Practice
------	---------------

3.14.1 Health Care PR actioners employed in the Public Service place their undivided attention, time and skills at the disposal of the Public Service as employer. Practitioners engaging in Remunerative Work Outside Public Service (RWOPS) shall do so in line with the approval by the executing authority; and in so doing, practitioners place the health and wellbeing of their patients as first priority.

3.14.2 Practitioners abusing RWOPS must be reported to Council.



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE IN THE HEALTH CARE
PROFESSIONS**

**GUIDELINES FOR THE MANAGEMENT OF HEALTH CARE
WASTE**

BOOKLET 12

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcs@hpcs.co.za

Website: <http://www.hpcs.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practice as a health care professional is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

GUIDELINES FOR GOOD PRACTICE IN THE HEALTH CARE PROFESSIONS	1
1 MOTIVATION OF THE NEED FOR THESE GUIDELINES	1
2 DEFINITION OF HEALTH CARE WASTE	1
3 TYPES OF HAZARDOUS HEALTH CARE WASTE	1
4 HAZARDOUS PROPERTIES OF HEALTH CARE WASTE.....	2
5 REASONS WHY HEALTH CARE WASTE IS A SIGNIFICANT DANGER TO SOCIETY	2
6 MANAGEMENT OF HEALTH CARE WASTE BY HEALTH CARE PRACTITIONERS.....	2
7 CONTACT DETAILS OF AUTHORITIES WHERE FURTHER ADVICE MAY BE OBTAINED	4
8 REFERENCES.....	5
1 SCOPE AND FIELD OF APPLICATION.....	3
2 DEFINITIONS	3
3 REFERENCE DOCUMENTS	8
4 OCCUPATIONAL HAZARDS AND HEALTH RISKS	9
5 GENERAL PROVISIONS.....	10
5.1 SEGREGATION OF WASTES.....	10
5.2 IN-HOUSE CONTROL	10
5.3 CLOSURE AND BAGGING OF WASTE-HOLDING PLASTIC BAGS.....	11
5.4 INTERMEDIATE AND FINAL STORAGE AREAS.....	11
5.5 MOVEMENT OF WASTE.....	11
5.6 DISPOSAL OF WASTE	12
5.7 MAINTENANCE AND CLEANING OPERATIONS	12
5.7.1.1 PROTECTIVE APPAREL	12
5.7.1.2 RUBBER BOOTS.....	12
5.7.1.3 REUSABLE WASTE CONTAINERS AND WASTE-MOVEMENT CARTS	12
5.7.2 STORAGE SITES	13
5.8 SPILL OR ACCIDENT CLEANUPS.....	13
6 SPECIFIC PROVISIONS FOR DEALING WITH THE DIFFERENT TYPES OF HEALTH CARE WASTE.....	14

6.4	THE FOLLOWING CATEGORIES OF HEALTH CARE WASTE ARE ADDRESSED IN THE STANDARD:	14
6.4.1	HUMAN/ANIMAL ANATOMICAL WASTE.....	14
6.4.2	INFECTIOUS NON-ANATOMICAL WASTE	14
6.4.3	SHARPS AND SIMILAR WASTE	14
6.4.4	CHEMICAL/PHARMACEUTICAL WASTE	15
6.4.5	RADIOACTIVE WASTE.....	15
6.4.6	PRESSURISED CONTAINER WASTE.....	16
6.4.7	GENERAL WASTE.....	16

GUIDELINES FOR THE MANAGEMENT OF HEALTH CARE WASTE BY HEALTH CARE PRACTITIONERS

1 MOTIVATION OF THE NEED FOR THESE GUIDELINES

The HPCSA views the proper disposal of health care waste by health care practitioners as an essential element of good professional practice. These guidelines are issued to remind practitioners of their ethical and professional obligations to their patients and to the community. They also serve to assist practitioners to meet the HPCSA's mandate to protect the public and the requirements of the South African Constitution (Act No.108 of 1996) regarding the preservation and protection of the environment.

2 DEFINITION OF HEALTH CARE WASTE

Health care waste may be defined as any undesirable or superfluous by-product, emission, residue or remainder generated by in the course of health care by healthcare professionals, healthcare facilities and other non-healthcare professionals, which is discarded, accumulated and stored with the purpose of eventually discarding it, or is stored with the purpose of recycling, re-using or extracting a usable product from such matter. Health care waste may, if handled improperly, have the potential to harm people, property or the environment. In this regard, all human anatomical waste, blood and body fluids are considered to be potentially hazardous. The unsafe disposal of such waste could have detrimental effects for people who might come into contact with health care waste.

3 TYPES OF HAZARDOUS HEALTH CARE WASTE

For the purpose of these guidelines, the following would be considered to be hazardous health care waste:

- 3.1 Infectious waste.
- 3.2 Pathological waste, including body fluids, secretions and surgical specimens.
- 3.3 Sharps, especially contaminated sharps.
- 3.4 Pharmaceutical waste.
- 3.5 Chemical waste.
- 3.6 Heavy metals.
- 3.7 Radioactive waste.
- 3.8 Genotoxic waste.
- 3.9 Cytotoxic agents
- 3.10 Pressurised containers.

4 HAZARDOUS PROPERTIES OF HEALTH CARE WASTE

Health care waste may be hazardous because it contains infectious, radioactive or toxic (including genotoxic, immunotoxic and cytotoxic) materials. Health care waste may also contain hazardous chemicals or pharmaceuticals and could be responsible for traumatic injury and other forms of physical hazard.

5 REASONS WHY HEALTH CARE WASTE IS A SIGNIFICANT DANGER TO SOCIETY

Health care waste is a significant danger to society because:

- 5.1 Unsafe management of hazardous health care waste, particularly in its disposal, may increase the risk of needle stick injuries, transmission of infectious agents and expose unsuspecting parties to unnecessary and entirely preventable risks. The severity of the risk associated with such exposures may be difficult to quantify, and such exposures should be prevented.
- 5.2 Health care waste entering the normal domestic waste stream will end up being disposed of in municipal landfill sites. When health care waste is placed in landfills or buried, contamination of groundwater may occur and may result in the spread of E-Coli and unacceptably high COD readings.
- 5.3. Many smaller landfill sites are not fenced off and have poor security. This results in unwanted tip-face picking and scavenging. If health care waste is disposed on such a site, there is a risk of exposure to people scavenging on the sites.
- 5.4 The irresponsible and illegal dumping of hazardous health care waste in South Africa, as intermittently reported in the media, is a matter of serious concern. It also places an unacceptably high financial and human resources burden on health authorities to manage the problem.
- 5.5 The burning of health care waste as opposed to incineration is not recommended as it pollutes the environment, especially through the formation of dioxins. Incineration should only be used where it meets specifications that avoid secondary pollutant emissions.

6 MANAGEMENT OF HEALTH CARE WASTE BY HEALTH CARE PRACTITIONERS

- 6.1 It is the responsibility of all health care practitioners to have a health care waste management system in place or to have access to such a system. Such a system should be provided by an accredited waste service provider and be conducted in accordance with relevant SANS code, such as 10248 -1- 2008 as updated. Such a system should deal comprehensively with measures for waste minimization, segregation, packaging, labeling, storage and removal under circumstances that do not pose a threat to human health or the environment, both for routine circumstances and in the event of an accident resulting in contamination with health care waste.
- 6.2 Independent practitioners should be able to provide demonstrable evidence of compliance with an acceptable protocol for the management of health care waste. Such a protocol should provide for an audit trail of the management of waste generated by the practice.
- 6.3 Where a health care practitioner is in the employ of a health care institution and is not directly responsible for the management policies of the facility, there is an

obligation on practitioners to insist that the management comply with the provisions of these guidelines. Where management is unable or unwilling to meet the requirements for safe management of health care waste, the practitioner should report the matter to the HPCSA and the Department of Health for appropriate follow up.

- 6.4 Provincial and local government health authorities should, wherever possible, by mutual agreement and taking into account the cost implications, make their facilities for the management of health care waste available to independent health care practitioners in the area.
- 6.5 Where a health care practitioner is responsible for the management of a health care facility, he or she must ensure that the facility has a documented waste management policy with sufficient resources and suitably trained team members to implement safe management of health care waste generated by the facility and its staff.
- 6.6 Health care practitioners should aim at all times to minimize the amount of health care waste generated in the process of health care delivery and to ensure that they are familiar with methods to minimize, segregate and store health care waste safely.
- 6.7 It is the responsibility of health care practitioners to ensure that, if necessary, they should keep up to date with the latest scientific knowledge on the safe management of health care waste by undergoing further training in waste management.
- 6.8 All medical sharps should be considered hazardous healthcare waste whether or not contaminated with infectious agents. The proper use and disposal of suitable sharps containers contributes to the minimization of injuries and transmission of potentially harmful agents. It is important that the health care practitioner make use of sharp containers that are suited for the purposes of disposing of sharps. Such containers should not puncture easily, should be stable and durable enough to withstand a fall onto a hard surface.
- 6.9 When using sharps containers for discarded needles and other sharp health care waste, health care practitioners should ensure that the containers are not filled beyond their fill capacity, and are maintained upright throughout their use during handling, storage and transport. Sharps that contain cytotoxic, genotoxic or radioactive waste should be treated as per their waste categories and not mixed with general sharp items. Do not reuse sharps containers designed, manufactured and intended for single-use purposes.
- 6.10 Health care practitioners have an obligation to report evidence of unsafe disposal or management of health care waste by other persons, including any health care practitioners, to the HPCSA and the Department of Health, should such unsafe practice come to their attention.
- 6.11 The Code of Practice of the South Africa Bureau of Standards on the Handling and Disposal of Waste Material within Health Care Facilities (SANS 10248 -1- 2008) or updates, should it be amended, should be used as a supplement to these official guidelines of the HPCSA for the management of health care waste by health care practitioners (see Annexure below).
- 6.12 Failure to adhere to these guidelines will be considered to be unprofessional conduct on the part of the health care practitioners concerned.

7	CONTACT DETAILS OF AUTHORITIES WHERE FURTHER ADVICE MAY BE OBTAINED
----------	--

- | | |
|--|---|
| <p>7.1 The Director-General
Department of Health
Private Bag X828
PRETORIA
0001
Tel: (012) 312-0921
Fax: (012) 323-0094</p> | <p>7.7 Environmental Health Office
Department of Health
Private Bag X517
BLOEMFONTEIN
9300
Tel: (051) 405-5021
Fax: (051) 448-1150</p> |
| <p>7.2 Provincial Environmental Health Office
Department of Health
Private Bag X0038
BISHO
5609
Tel: (040) 609-3701
Fax: (040) 635-0115</p> | <p>7.8 Environmental Health Office
Department of Health and Welfare
Private Bag X2068
MMABATHO
2735
Tel: (018) 387-5096
Fax: (018) 387-5332</p> |
| <p>7.3 Environmental Health Office
Department of Health
Private Bag X11285
NELSPRUIT
1200
Tel: (013) 752-8085 x 2043
Fax: (013) 755-3549</p> | <p>7.9 Environmental Health Office
Department of Health
P O Box 62302
MARSHALLTOWN
2107
Tel: (011) 355-3829
Fax: (011) 355-3154</p> |
| <p>7.4 Environmental Health Office
Department of Health
Private Bag X9051
PIETERMARITZBURG
3201
Tel: (033) 395-2772
Fax: (033) 342-1405</p> | <p>7.10 Environmental Health Office
Department of Health
P O Box 648
CAPE TOWN
8000
Tel: (021) 483-3737
Fax: (021) 483-2786</p> |
| <p>7.5 Environmental Health Office
Department of Welfare
Private Bag X5048
KIMBERLEY
8300
Tel: (053) 830-0654
Fax: (053) 830-0655</p> | <p>7.11 The Director General
Department of Environmental Affairs
and Tourism
Fedsure Forum
315 Pretorius Street
Private Bag X477
PRETORIA
0001</p> |
| <p>7.6 Environmental Health Office
Department of Health and Welfare
Private Bag X9302
POLOKWANE
0700
Tel: (015) 290-9057
Fax: (015) 291-2925</p> | <p>7.12 The President
South African Institute of
Environmental Health
P O Box 23
NIGEL
1490</p> |

8	REFERENCES
----------	-------------------

- 8.1 Mudgal, S; De Toni, A; Lockwood, S; Salês, K; Backhaus,T & Sorensen, BH. Study on the environmental risks of medicinal products – Final Report. December 2013. Available from: http://ec.europa.eu/health/files/environment/study_environment.pdf [Accessed on 19 May 2015]
- 8.2 Mathee A. Environment and Health in South Africa: Gains, Losses and Opportunities. Journal of Public Health Policy. 2011. 32, s37- s43. DOI: 10.1057/jphp.2011.21
- 8.3 South African National Standards (A division of SABS): Management of healthcare waste. Part 1: Management of healthcare Risk Waste from a Healthcare facility. SANS Code 10248-1-2008, Pretoria. 2008.
- 8.4 Gabela, S D. Health Care Waste Management in Public Clinics in the ILembe District. A Situational Analysis and Intervention Strategy. Health Systems Trust, University of Kwazulu Natal. National Department of Health. 2007. <http://www.hst.org.za> [accessed on 16 May 2015]
- 8.5 Oelofse, S & Musee, N. Hazardous Waste Management and Emerging Waste Streams: A Consideration of Key Emerging Issues that may Impact the State of the Environment. CSIR, Natural Resources and the Environment. March 2008. ISBN No: 978-0-9814178-3-7

**I suggest we replace with SANS 10248-1-2008 with annexures
A.B, D & F**

ANNEXURE

ABRIDGED VERSION

UDC 725.5:628.4.04

SABS 0248:1993

SOUTH AFRICAN BUREAU OF STANDARDS

CODE OF PRACTICE

for the

**HANDLING AND DISPOSAL OF WASTE MATERIALS WITHIN HEALTH CARE
FACILITIES**

(Incorporating CAN/CSA-Z317.10-88, *Handling of waste materials within health care
facilities*, with modifications)

Abridged by the
Health Professions Council of South Africa
as part of the
Guidelines for the Management of Health Care Waste by Medical Practitioners, Dentists
and Medical Scientists

The detailed document is
obtainable from the

SA BUREAU OF STANDARDS
Private Bag X191
Pretoria
Republic of South Africa
0001

Tel: (012) 428-6561
Fax: (012) 344-1568

NOTICE

The detailed standard was approved by the Council of the South African Bureau of Standards on 25 February 1993. It remains under revision and should, therefore, be obtained from the Bureau in full if required for verification of specific provisions.

NOTES

1. In terms of the Regulations promulgated under the Standards Act, 1982 (Act No. 30 of 1982), it is a punishable offence for any person to falsely claim compliance with the provisions of a code of practice published by the South African Bureau of Standards.
2. Authorities who wish to incorporate any part of this code of practice into any legislation in the manner intended by section 33 of the Act, should consult the South African Bureau of Standards regarding the implications.
3. As the standard will be revised when necessary in order to keep abreast of progress, comment will be welcomed by the Bureau and will be considered when the standard is revised.

FOREWORD

The standard establishes specific guidelines for the segregation, collection, movement and storage of waste materials within health care facilities. The main objective is to decrease injury to personnel and the possible risks of spreading infection due to the improper handling of waste materials.

The main features of the standard are as follows:

1. A series of waste categories based on the World Health Organisation's Report *Management of Waste from Hospitals* has been introduced.
2. A clause on pharmaceutical waste appears in the standard.
3. A classification system for waste containers has been developed.
4. Various procedures reflect modern current infection control practices.
5. The standard has been written in such a way as to reflect the practical aspects of handling waste.

INTRODUCTION

In many guidelines, all waste contaminated with blood or body fluids are classified as infectious waste. This enormously increases the volume of waste requiring expensive handling and disposal. Identical items of waste are disposed of from homes with no special handling or decontamination. For these reasons, this issue received detailed consideration during the preparation of the standard.

The identification of every patient who carries a blood borne pathogen such as Hepatitis B or Human Immunodeficiency Virus (HIV, leading to AIDS) is both impractical and inappropriate. The modern trend in hospital infection control is to build safe practices into ALL clinical procedures; the precaution taken is dictated by the risk accompanying the procedure, not by the diagnosis.

Two premises have been incorporated throughout the standard:

1. The simple presence of viable organisms does not constitute a hazard; a mechanism by which these organisms can infect a host must coexist. Since Hepatitis B and HIV are usually transmitted by inoculation, the concern with blood alone, for example, is misplaced. The emphasis should more appropriately be applied to the category of clinical sharps. Infections acquired by waste handlers are rare, but almost always associated with trauma. Vigorous efforts directed toward the prevention of these injuries deserve high priority; the incidence of both the wounds and accompanying infections can be reduced dramatically by adherence to safe procedures.
2. Absolute elimination of all risk is impossible. A realistic goal is the attainment of a reasonable degree of safety at all times without needlessly compromising efficiency.

Note: The scope of the standard is restricted to the health care site, but the responsible person for the health care facility still bears the ultimate responsibility for the safe disposal of waste (generated on site) outside the site.

1 SCOPE AND FIELD OF APPLICATION

- 1.1 The standard includes criteria for the segregation, collection, movement, storage, and on-site disposal of waste materials within health care and biological research facilities.
- 1.2 The standard does not deal with the disposal of waste once it has been removed from the site of the health care facility. Such matters are the subject of national, provincial, regional and municipal legislation and regulations.
- 1.3 The standard does not address special precautions in national and provincial legislation which may apply to infectious substances (or the transportation thereof).
- 1.4 In the standard, "shall" indicates a mandatory requirement; "should" indicates a recommendation, or that which is advised but not mandatory.
- 1.5 Notes accompanying the clauses do not include mandatory or alternative requirements. The purpose of a note accompanying a clause is to separate it from the text as being explanatory or informative material that is not properly a part of the standard. Notes to the table are considered to be part of the table and are written as mandatory requirements.

2 DEFINITIONS

The following definitions apply to the standard and are included herein for information and clarity:

- 2.1 **Chemical waste:** Comprises discarded solid, liquid and gaseous chemicals, e.g. from diagnostic or experiential work, or from cleaning, housekeeping or disinfecting procedures. Chemical waste may be hazardous or non-hazardous. For the purposes of choosing the most appropriate waste-handling method, hazardous chemical waste is considered to be waste that is -

2.1.1 Toxic;

2.1.2 Corrosive (acids of pH < 2,0 and bases of pH > 12,0);

2.1.3 Flammable;

2.2.4 Reactive (explosive, water reactive, shock sensitive); or

2.2.5 Genotoxic (carcinogenic, mutagenic, teratogenic or otherwise capable of altering genetic material).

[Note: Non-hazardous chemical waste consists of chemicals other than those described here, such as sugars, amino acids, and certain organic and inorganic salts].

2.2 **Clinical glass:** Glass possibly contaminated with blood and body fluids or chemicals, (e.g. blood collection tubes, laboratory glass, medication vials).

2.3 **Collection:** The accumulation of wastes from several primary or intermediate storage sites for movement to a waste-holding area or from several waste-holding areas for movement to a final storage area.

2.4 **Colour-coding:** The application of colour to a container in order to identify the category of waste for which it is to be used.

2.5 **Container:** Any receptacle for the storage of wastes. Containers can be classified into two subgroups as follows:

2.5.1 Reusable waste container.

2.5.2 Single-use waste container.

2.5.1. **Reusable waste container:** A waste container that is:

2.5.1.1 Reusable;

2.5.1.2 Fabricated of metal or rigid plastics;

2.5.1.3 Resistant to burning, impact and corrosion;

2.5.1.4 Suitable for the waste it is to contain; and

2.5.1.4 Colour-coded or identified according to the type of waste for which it is intended (see table 1) by one of the following methods:

1. If the container is made of plastics, the plastics may be dyed in the appropriate colour; or
2. A band of colour not less than 50 mm in width may be applied to the container. Reusable waste containers shall be inspected for holes or leaks every time they are emptied, and their colour-coding renewed if necessary.

[Note: Such containers are used for the:

- a. Collection;
- b. Transportation; or
- c. Storage of waste, e.g. garbage cans and storage bins].

2.5.2 **Single-use waste container:** A waste container that can be one of the following:

2.5.2.1 Sharps container.

2.5.2.2 Waste-holding plastic bag.

2.5.2.3 Cardboard container.

2.5.2.4 Specialised container.

2.5.3 **Sharps container:** A container that:

2.5.3.1 Is sturdy enough to resist puncture under usage conditions and to the point of disposal;

2.5.3.2 Is clearly identified as containing sharps, e.g. by the use of the word SHARPS or a symbol recognised by the facility;

2.5.3.4 Has lid(s) capable of being tightly secured; and

2.5.3.5 If used for containing cytotoxic wastes, has the cytotoxic hazard symbol displayed clearly and visibly.

[Notes:

1. Other useful features of sharps containers include -

- a. A fill line;
- b. Unauthorised withdrawal prevention;
- c. Handles; and
- d. A wall bracket and lock.

2. Containers selected should be compatible with and appropriate to the type of waste they are to contain.

3. Where practical, the same type of container should be used throughout a facility. Standardisation of the containers will encourage greater use and enhance identifiability among users].

2.5.4 **Waste-holding plastic bag container:** A plastics bag used as a container and that is:

2.5.4.1 Colour-coded or identified according to the type of waste for which it is intended (see table 1); and

2.5.4.2 Sturdy enough to resist puncture, leaking and breaking under individual usage conditions and to the point of disposal, except where:

- a. Provincial regulations governing the off-site disposal of waste require bags of a specific thickness;
- b. Municipal or other local authorities responsible for sanitary landfill sites require bags of a specific thickness; or
- c. Facility administrators have established procedures involving specified bag thicknesses.

[Note: It is inappropriate to specify a minimum thickness of plastic bags or plastic sharps containers since polymeric materials vary extensively in their physical and mechanical properties. It is quite possible that a 25 mm thick film of one polymeric material will be more puncture, impact and abrasion resistant than a 50 mm thick film of a different polymeric material. These properties can be further affected by the manufacturing process, i.e. extrusion and injection moulding. The most appropriate manner of determining the suitability of a particular container in respect of its ability to resist puncture, leaking and breaking under individual usage conditions is to subject the container to those usage conditions].

2.5.5 Cardboard container: A container made from cardboard and that is:

2.5.5.1 Colour-coded or identified according to the type of waste for which it is intended (see table 1);

2.5.5.2 Rigid; and

2.5.5.3 Leak resistant.

2.5.6 Specialised containers (e.g. paint cans): Specialised containers colour-coded or identified according to the type of waste for which they are intended.

2.6 Cytotoxic: Having a deleterious effect upon cells; commonly used in reference to pharmaceuticals used in the treatment of cancer, (e.g. antineoplastics, chemotherapy agents).

2.7 Disposal: The removal of waste from the site of the health care facility or the on-site incineration of waste.

2.8 General waste: Waste that:

2.8.1 Has not been included in the other waste categories; and

2.8.2 Does not pose a disease-related risk or threat to people or the environment.
The general waste category includes:

2.8.2.1 Office waste;

2.8.2.2 Kitchen waste;

2.8.2.3 Non-clinical glass waste; and

2.8.2.4 All other similar wastes.

2.9 Hazardous: Referring to any material or substance that, if handled improperly, has the potential to harm people, property or the environment.

[Note: All human anatomical waste such as blood and body fluids are potentially hazardous.

2.10 Human/animal anatomical waste:

2.10.1 Waste consisting of:

2.10.1.1 Tissues;

2.10.1.2 Organs;

- 2.10.1.3 Body parts;
- 2.10.1.4 Products of conception; and
- 2.10.1.5 Animal carcasses.

2.10.2 This waste category is divided into the subcategories of:

- 2.10.2.1 Human anatomical waste;
- 2.10.2.2 Infectious animal anatomical waste; or
- 2.10.2.3 Non-infectious animal anatomical waste.

[Note: The following are considered to be non-anatomical wastes:

- a. Blood and body fluids.
- b. Extracted teeth.
- c. Nail clippings.
- d. Hair].

2.11 **Health care facilities:** Health care facilities are all places (sites) where professional health services are dispensed to human patients or biological research is carried out and includes, *inter alia*, hospitals, clinics, rehabilitation centres, sick bays (old age homes), free-standing operating theatres, day units, clinics (mobile and stationary) and doctor's consulting rooms.

2.12 **Infectious non-anatomical waste:** Any waste contaminated with viable micro-organisms capable of transmitting, and reasonably likely to transmit, disease.

[Note: This may include -

- a. All microbiology lab wastes that have not been decontaminated;
- b. Waste from surgeries and autopsies performed on patients with infectious diseases; and
- c. All contaminated waste from patients].

2.13 **Movement:** Transfer of waste material between storage areas within the health care facility.

2.14 **Non-clinical glass:** Glass from maintenance and kitchen areas, (e.g. broken window panes and discarded glass bottles, unless visibly contaminated with blood).

2.15 **Pharmaceutical waste:** Pharmaceutical products such as drugs and medicinal chemicals that are:

- 2.15.1 No longer usable in patient treatment and have been returned from patient care areas, have become outdated or contaminated, have been stored improper; or

- 2.15.2 No longer required.
- 2.16 **Pressurised container waste:** Consists of aerosol cans or disposable compressed gas containers that may explode if incinerated or accidentally punctured.
- 2.17 **Refrigerated storage:** Storage of waste at a temperature of 4°C or lower.
- 2.18 **Segregation:** The separation of waste according to classification (see Table 1) prior to storage.
- 2.19 **Sharps and similar waste:** These include:
- 2.19.1 Needles;
 - 2.19.2 Syringes;
 - 2.19.3 Blades;
 - 2.19.4 Clinical glass; and
 - 2.19.5 Any other clinical items capable of causing a cut or puncture.
- 2.20 **Soiled utility room:** An intermediate storage room within the facility where waste from the patient's bedside is temporarily stored.
- 2.21 **Storage:** The accumulation of waste after segregation in a specified container in a predetermined location.
- 2.22 **Storage areas:**
- 2.22.1 **Final storage area:** The area of the facility where waste is stored just before being disposed of;
 - 2.22.2 **Intermediate storage area:** The area of the facility where waste is stored following its collection from the primary storage area and before being removed to the final storage area. This will necessarily include the means by which the waste is transported;
 - 2.22.3 **primary storage area:** The area of the facility where waste originates, e.g. a consulting room, patient room and laboratory.
- 2.23 **System:** The waste management system belonging to the health care facility.
- 2.24 **Waste holding:** The storage of waste collected from all primary storage areas such as a laboratory wing, a block of operating rooms, or a floor of patient rooms.

3 REFERENCE DOCUMENTS

- 3.1 The following documents should be referred to when handling and disposing of waste materials:
- 3.1.1 *Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965).*

- 3.1.2. *Human Tissue Act*, 1983 (Act No. 56 of 1983), as amended.
- 3.1.3 Compulsory specification for biological safety cabinets (Classes I, II and III), published by Government Notice No. 1318 (*Government Gazette* No. 12517) of 15 June 1990.
- 3.1.4 SABS 1186, *Symbolic safety signs*.
- 3.1.5 SABS 0226, *The installation, post-installation tests and maintenance of biological safety cabinets*.
- 3.1.6 BS 5252, *Framework for colour coordination for building purposes*.

4 OCCUPATIONAL HAZARDS AND HEALTH RISKS
--

- 4.1 To minimise the occupational health risks associated with the handling and disposal of health care waste, occupational health care programmes should:
 - 4.1.1 Introduce safe or less hazardous substitutes for chemical agents with exposure hazards;
 - 4.1.2 Require closed storage for volatile agents, traces of which, or brief exposure to which, cause a health hazard;
 - 4.1.3 Require the use of proper venting and exhausting in accordance with the established principles of occupational hygiene;
 - 4.1.4 Provide appropriate personal protective equipment with disinfection and disposal arrangements for workers involved in various stages of waste handling and disposal;
 - 4.1.5 Include an assessment of waste management procedures on a regular basis, to assure compliance with the standard and applicable national, provincial, regional and municipal regulations and legislation;
 - 4.1.6 Include a training programme for all persons handling wastes;
 - 4.1.7 Include appropriate protective equipment and handwashing facilities; and
 - 4.1.8 Include a written procedure to handle and report needle-stick injuries and other injuries sustained whilst engaged in waste disposal.
- 4.2 Health care facilities shall have freely available to all personnel concerned, written policies and procedures which include requirements for at least:
 - 4.2.1 The cautionary labeling of all containers of hazardous materials;
 - 4.2.2 Material safety data sheets;
 - 4.2.3 Appropriate worker training for each system element;
 - 4.2.4 Protection of proprietary information; and
 - 4.2.5 When applicable, compliance with relevant national and local regulations.

5 GENERAL PROVISIONS

All waste needs to be handled so as to ensure that it is segregated at source, contained in packaging that holds the contents to the point of disposal, and disposed of in a manner that is practical and efficient yet minimises any hazard. By minimising the handling of waste, fewer people will be exposed to it. Potentially offensive unrefrigerated waste should be timeously removed.

There are certain classes of waste that need to be handled in specific ways. They are specified in the standard to ensure proper handling.

5.1 SEGREGATION OF WASTES

Wastes shall be segregated according to the following categories that are further detailed in Table 1 (see below page 16):

- 5.1.1 Human/animal anatomical waste.
- 5.1.2 Infectious non-anatomical waste.
- 5.1.3 Sharps and similar waste.
- 5.1.4 Chemical/pharmaceutical waste.
- 5.1.5 Radioactive waste.
- 5.1.6 Pressurised container waste.
- 5.1.7 General waste.

5.2 IN-HOUSE CONTROL

- 5.2.1 Each generator of biohazardous waste shall prepare, maintain and implement a written plan to identify and handle all waste generated within the facility and shall provide a training programme for all staff to familiarise them with:
 - 5.2.1.1 Procedures for the segregation, collection, storage, labeling and movement of waste specified by the standard;
 - 5.2.1.2 Personal hygiene, especially handwashing; and
 - 5.2.1.3 The hazards of those materials to which workers may be exposed. Such training shall be continuously assessed and reinforced.
- 5.2.2 An inspection programme shall be established to ensure that the procedures specified by the standard are followed.
- 5.2.3 The final disposal of hazardous waste remains the responsibility of the waste generator.

[Note: The in-house control of waste produced by health care facilities should be managed in accordance with the provisions of the standard, under the supervision of the facility's infection control committee or a designated department].

5.3 CLOSURE AND BAGGING OF WASTE-HOLDING PLASTIC BAGS

- 5.3.1 Bags containing waste, no matter how they are closed, shall be such that their contents are prevented from escaping.
- 5.3.2 A single bag is normally adequate if it is impervious and sturdy (i.e. not easily penetrated) and if the article can be placed in the bag without contaminating the outside of the bag. Otherwise, double bagging should be used.

5.4 INTERMEDIATE AND FINAL STORAGE AREAS

- 5.4.1 All waste-storage areas shall meet the requirements of the National Building Regulations.
- 5.4.2 Intermediate and final storage areas shall:
 - 5.4.2.1 Be totally enclosed;
 - 5.4.2.2 Be separate from supply rooms or food preparation areas;
 - 5.4.2.3 Have provision for being locked; and
 - 5.4.2.4 Have access restricted to authorised personnel only.
- 5.4.3 Health care facilities that refrigerate stored waste shall use:
 - 5.4.3.1 A lockable, closed cold storage facility; or
 - 5.4.3.2 A lockable, domestic-type freezer unit that is dedicated to the accumulation of waste for disposal. This waste shall be stored at a temperature of 4°C or lower, with freezing being the preferred method of storage.
- 5.4.4 Health care facilities shall prepare a contingency plan for dealing with the storage of refrigerated waste in the event of excess waste being produced, incineration facilities or refrigeration/freezing facilities becoming inoperative.
- 5.4.5 Health care facilities shall prepare a contingency plan to deal with the disposal of waste in the event of a disruption of disposal services.
- 5.4.6 Users of the standard shall refer to the National Building Regulations for information regarding the ventilation of waste-storage areas.

5.5 MOVEMENT OF WASTE

- 5.5.1 Manual handling of waste materials shall be minimised.
- 5.5.2 Carts used for carrying waste shall be:
 - 5.5.2.1 Capable of containing the waste;
 - 5.5.2.2 Designed to prevent spills; and

5.5.2.3 Constructed of materials that permit effective cleaning and disinfection.

[Note: Open carts may be used to transfer waste contained within waste containers].

5.5.3 Waste containers shall be moved only when properly closed.

5.5.4 Specific routes for the movement of waste shall be planned in order to minimise its passage through patient care and other clean areas.

5.5.5 Waste disposal chutes should be avoided, but if they are provided, shall be used for general waste purposes only. Such disposal chutes shall comply with all applicable building and fire codes and regulations.

5.5.6 The compacting of waste destined for landfill sites shall be determined by the individual health care facility in accordance with national, provincial, regional and municipal legislation and regulations.

5.6 DISPOSAL OF WASTE

The health care facility shall dispose of all waste in accordance with national, provincial, regional and municipal regulations and legislation.

5.7 MAINTENANCE AND CLEANING OPERATIONS

5.7.1.1 Protective apparel

The following protective apparel shall be worn, as necessary, by any personnel engaged in the cleaning of reusable waste containers, waste-movement carts, or final storage areas:

5.7.1.1 Water-resistant coveralls.

5.7.1.2 Rubber boots.

5.7.1.3 Heavy-duty waterproof gloves.

5.7.1.4 Protective goggles or face shields.

[Note: When not in use, protective apparel shall be stored in an area designated for this purpose].

5.7.1.3 Reusable waste containers and waste-movement carts

5.7.2.1 Reusable waste containers and waste-movement carts shall be thoroughly cleaned in accordance with the facility's established procedures.

5.7.2.2 The frequency of cleaning operations shall be in accordance with the facility's established procedures.

5.7.2.3 Reusable waste containers and waste-movement carts shall be thoroughly cleaned before any maintenance work is performed on them.

5.7.2 Storage sites

Floors, walls and ceilings of intermediate and final storage areas shall be thoroughly cleaned in accordance with the facility's established procedures.

5.8 SPILL OR ACCIDENT CLEANUPS

- 5.8.1 Every possible effort should be made to avoid the escape of any hazardous material in the course of normal operations. Minor spills involving loss or release into the air of small volumes of material are most likely to result from faulty transfer techniques. Major spills or accidents usually involve container rupture, caused by equipment malfunction or careless handling.
- 5.8.2 As in the handling of all hazardous substances, the most important elements in dealing with a major spill are common sense and a contingency plan prepared and learned in advance.
- 5.8.3 Health care facilities shall have a documented policy and procedure for managing spills of a hazardous substance.
- 5.8.4 The procedure for managing a spill shall include the following:
- 5.8.4.1 All staff shall be trained and educated in -
- a. The management of hazardous substances; and
 - b.. The recognition and management of a spill condition.
- 5.8.4.2 A method for the containment and isolation of each type of spill shall be prepared.
- 5.8.4.3 Should a spill occur, the person or persons designated for spill cleanup shall be notified immediately. These persons shall have specific training in the management of spills.
- 5.8.4.4 Information concerning individual substances and their cleanup shall be readily accessible to all staff and available on a 24 hour basis.
- 5.8.4.5 Proper equipment shall be made available for:
- a. Spill cleanups; and
 - b. The protection of employees.
- 5.8.4.6 The procedures for each type of spill shall be documented and made available in the area where the spill is likely to occur.
- 5.8.4.7 Procedures for the proper disposal of waste spills according to the waste-management policy of the facility shall be prepared.
- 5.8.4.8 All incidents shall be documented for the purpose of record keeping.
- 5.8.4.9 Any employee exposed to a spill shall be treated and monitored by the facility.

5.8.4.10 If necessary, evacuation and internal disaster plans shall be implemented.

6	SPECIFIC PROVISIONS FOR DEALING WITH THE DIFFERENT TYPES OF HEALTH CARE WASTE
----------	--

- 6.1 After dealing with the above general provisions, the standard goes on to deal separately with each of the various categories of health care and general waste.
- 6.2 Readers who require more detailed information on dealing with the relevant categories of waste, are advised to contact the South African Bureau of Standards (SABS) for such information as the standard for dealing with health care waste is constantly under review and being updated as required.
- 6.3 At the invitation of the SABS, a member of the HPCSA's Committee for Human Rights, Ethics and Professional Practice has been nominated to serve on the relevant Committee of the SABS. The HPCSA appreciates this invitation and trusts that it will result in close cooperation between the SABS and the HPCSA in dealing with this important aspect of health care management and protection of the public.

6.4 The following categories of health care waste are addressed in the standard:

6.4.1 Human/animal anatomical waste

The standard deals with its definition and the following subcategories:

6.4.1.1 Human anatomical waste

The item deals with the containment, collection, final storage areas and disposal of human anatomical waste.

6.4.1.2 Animal anatomical waste

The item deals with the containment, collection, final storage areas and disposal of animal anatomical waste.

6.4.2 Infectious non-anatomical waste

The standard deals with the definition, containment, collection, final storage areas and disposal of infectious non-anatomical waste.

6.4.3 Sharps and similar waste

The standard deals with the definition of sharps and similar waste which includes:

6.4.3.1 Needles;

6.4.3.2 Syringes;

6.4.3.3 Blades;

6.4.3.4 Clinical glass; and

6.4.3.5 Any other clinical items capable of causing a cut or puncture; and

their containment, collection and disposal.

6.4.4 Chemical/pharmaceutical waste

The standard on chemical waste deals mainly with hazardous and pharmaceutical chemicals, their definition, basic safety guidelines, basic waste disposal guidelines, the handling and disposal of pharmaceuticals other than cytotoxics, and the handling and disposal of cytotoxic pharmaceuticals.

6.4.5 Radioactive waste

The handling and disposal of radioactive wastes are subject to the Nuclear Energy Act, 1982 (Act No. 92 of 1982).

6.4.6 Pressurised container waste

The standard again deals with the definition, containment, collection and disposal of pressurised container waste.

6.4.7 General waste

The standard deals with the definition, containment, collection and disposal of general waste and briefly addresses the issues of kitchen waste and non-clinical glass waste.

TABLE 1 - SUMMARY OF COLOUR-CODING/LABELING REQUIREMENTS

1	2	3	4
Waste category	Waste subcategory	Colour-coding/labeling	Clause
1. Human/animal*) anatomical waste	1(a) Human anatomical	RED	6.2
	1(b) Infectious animal anatomical	ORANGE**, OR RED	6.3
	1(c) Non-infectious animal anatomical	BLUE	6.3
2. Infectious*) non-anatomical waste		YELLOW	7
3. Sharps and similar waste		"SHARPS" or recognised symbol	8
4. Chemical/ pharmaceutical waste	Chemical waste		9.1/9.2
	Pharmaceutical waste excluding cytotoxic pharmaceutical waste	BLACK, DARK GREEN, or recognised coding	9.3/9.3.4
	Cytotoxic pharmaceutical waste	Cytotoxic hazard symbol	9.3.5
5. Radioactive waste		Radiation hazard symbol	10
6. Pressurised container waste		BLACK or DARK GREEN	11
7. General waste	7(a) Office waste	BLACK or DARK GREEN	12
	7(b) Kitchen waste	BLACK or DARK GREEN	12.4
	7(c) Non-clinical glass waste	BLACK or DARK GREEN	12.5
	7(d) Non-infectious non-anatomical waste	BLACK or DARK GREEN	12
*) Chemical or radioactive solutions containing human/animal anatomical and infectious non-anatomical wastes should be considered as chemical or radioactive wastes respectively.			
**) ORANGE - 06E53 in BS 5252 (MUNSELL Ref 5YR7/15).			

ISBN 978-0-626-21200-1

SANS 10248-1:2008

Edition 1

SOUTH AFRICAN NATIONAL STANDARD

Management of healthcare waste

Part 1: Management of healthcare risk waste from a healthcare facility

Published by Standards South Africa
1 dr lategan road groenkloof ☒ private bag x191 pretoria 0001
tel: 012 428 7911 fax: 012 344 1568 international code + 27 12
www.stansa.co.za
© Standards South Africa

standards
SouthAfrica
(a division of SABS)

SANS 10248-1:2008

Edition 1

Table of changes

Change No.	Date	Scope

Foreword

This South African standard was approved by National Committee StanSA SC 5140.06M, *National committee for dangerous goods standards – Disposal of healthcare waste*, in accordance with procedures of Standards South Africa, in compliance with annex 3 of the WTO/TBT agreement.

This document was published in May 2008. This document supersedes SANS 10248 (edition 2).

SANS 10248 consists of the following parts, under the general title *Management of healthcare waste*:

Part 1: Management of healthcare risk waste from a healthcare facility.

Part 2: (in course of preparation).

Part 3: (in course of preparation).

Annexes A, B, D and F form an integral part of this document. Annexes C and E are for information only.

Introduction

This part of SANS 10248 presents the basic elements for the management of healthcare risk waste. In this respect certain issues are considered to be of importance for the successful application of this standard, namely

- a) the need to deal with the management aspects of healthcare risk waste in addition to the technical operation of healthcare risk waste disposal,
- b) the need for a document suitable for audit purposes that can be administered to fulfil the needs of the generators which might have greatly varying resources,
- c) the need to control the potential hazards from chemicals, materials that emit ionising radiation and the spread of infectious diseases that can place the public and especially waste disposal workers at risk,
- d) the need for guidelines covering the entire cycle, including waste minimization, point of use disposal through internal and external transportation to final treatment and disposal, and
- e) the need for an environmental management policy.

Contents

Foreword	
Introduction	
1 Scope	3
2 Normative references	3
3 Definitions and abbreviations	4
4 Requirements	9
4.1 Management requirements	9
4.2 Requirements for the waste management team	10
5 The waste management plan	13
5.1 General	13
5.2 Documentation requirements	14
5.3 Contractual commitments	15
5.4 Work procedures and work instructions	15
5.5 Inspection and quality control	16
5.6 Health and safety policy	16
5.7 Training	17
5.8 Workplace hygiene	17
6 Identification, classification, segregation, collection and minimization of healthcare waste	18
6.1 Identification	18
6.2 Classification	19
6.3 Waste segregation	19
6.4 Collection	19
6.5 Waste minimization	19
7 Packaging	21
7.1 Packaging requirements for healthcare general waste	21
7.2 Packaging requirements for healthcare risk waste	21
7.3 Colour coding of packaging	21
7.4 Packaging for infectious waste (excluding sharps)	22
7.5 Packaging for sharps	23
7.6 Packaging for chemical waste	23
8 Waste storage	28
8.1 Temporary healthcare risk waste stores	28
8.2 Central healthcare risk waste stores	28
8.3 Provisions for the storage of infectious waste and non-infectious anatomical waste	30
8.4 Provisions for the storage of chemical and pharmaceutical waste	30
8.5 Provisions for the storage of radioactive waste	31
8.6 Provisions for the storage of healthcare general waste	31
9 Collection and transportation of healthcare risk waste	31

SANS 10248-1:2008

Edition 1

9.1	Collection of healthcare risk waste within a healthcare facility	31
9.2	Transportation of healthcare risk waste within a healthcare facility.....	32
9.3	Collection of healthcare risk waste for off-site transportation	32
9.4	Off-site transportation of healthcare risk waste	33
10	Spillage of healthcare risk waste during transportation.....	33
10.1	Policy and strategies.....	33
10.2	Clean-up procedures for infectious waste and hazardous chemical waste spills.....	34
10.3	Clean-up procedures for cytotoxic pharmaceutical waste spills.....	34
11	Treatment and disposal methods	35
11.1	General	35
11.2	Disposal via discharge to a municipal sewer	35
11.3	Disposal of healthcare risk waste by incineration	36
11.4	Disposal of healthcare risk waste by alternative technologies.....	37
11.5	Authorized treatment facilities operated on-site at healthcare facilities.....	37
11.6	Authorized treatment facilities operated off-site from healthcare facilities.....	38
Annex A	(normative) National legislation and other publications	39
Annex B	(normative) Contractual commitments	40
Annex C	(informative) Examples of documents	41
Annex D	(normative) Hazard classes and hazard rating	44
Annex E	(informative) 'Green' procurement.....	46
Annex F	(normative) Hazard labelling.....	49
Bibliography	54

Management of healthcare waste

Part 1:

Management of healthcare risk waste from a healthcare facility

1 Scope

This standard lays down minimum provisions for the safe and effective management of healthcare risk waste generated by healthcare facilities and other places where healthcare professionals work in order to reduce potential risks to humans and to the environment. The management of healthcare risk waste covers the generation, the packaging, the treatment and the disposal (cradle-to-grave) of the waste.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. Information on currently valid national and international standards can be obtained from Standards South Africa.

2.1 Standards

SANS 452, *Reusable and non-reusable sharps containers* (in course of preparation).

SANS 1518, *Transport of dangerous goods – Design, construction, testing, approval and maintenance for road vehicles and portable tanks.*

SANS 10228, *The identification and classification of dangerous goods for transport.*

SANS 10229-1, *Transport of dangerous goods – Packaging and large packaging for road and rail transport – Part 1: Packaging.*

SANS 10231, *Transport of dangerous goods – Operational requirements for road vehicles.*

SANS 10232-1, *Transport of dangerous goods – Emergency information systems – Part 1: Emergency information system for road transport.*

SANS 10232-3, *Transport of dangerous goods – Emergency information systems – Part 3: Emergency response guides.*

SANS 10233 (SABS 0233), *Transportation of dangerous goods – Intermediate bulk containers.*

2.2 Other publications

Natural Colour Institute (NCS), Scandinavian Colour Institute.

Pantone color formula guide 1000. Moonachie, NJ: Pantone Inc. 1991.

3 Definitions and abbreviations

For the purposes of this document, the following definitions and abbreviations apply.

3.1 Definitions

3.1.1

alternative technology

approved method, technique or process for microbial inactivation or for otherwise altering the biological, chemical or physical characteristics of healthcare risk waste to sterilize such healthcare risk waste by means of technology which do not constitute controlled combustion treatment

3.1.2

approved

acceptable to the relevant approving authority

3.1.3

authorized

approved by the relevant governmental department in accordance with the relevant national legislations and regulations

3.1.4

calorific value

heating value

quantity of heat that is produced when a unit mass of a material undergoes complete combustion under certain specified conditions and expressed in terms of calories or joules per kilogram (MJ/kg for solids and liquids and MJ/m³ for gases)

3.1.5

capacity

optimal quantity of waste that can be processed in a given time under specified conditions, usually expressed in terms of mass per 24 h

3.1.6

chief executive officer

CEO

person responsible for the overall management and control of a healthcare facility

3.1.7

clinical glass

glass that might be contaminated with blood, body fluids or chemicals, e.g, blood collection tubes, laboratory glassware and medication vials

3.1.8

collection

accumulation of wastes from intermediate storage sites for movement to a primary waste holding area or from several primary waste holding areas to the treatment or final disposal site (or both)

3.1.9

colour coding

use of colour on a container or bag or the label attached to such, that serves to identify the category of waste that it contains

3.1.10

container

disposable or reusable vessel in which waste is placed for handling, transportation, storage, or eventual treatment or disposal (or both)

3.1.11

cytotoxic

agent that has a toxic effect on cells, causing cell death or disruption

3.1.12

decontamination

process or mode of action to reduce contamination to a safe level

3.1.13

disinfectant

chemical agent that is able to reduce the number of viable micro-organisms

3.1.14

disinfection

process or mode of action whereby the number of viable micro-organisms are reduced to safe or relatively safe levels

NOTE 1 High-level disinfection is when all micro-organisms, with the exception of small numbers of bacterial spores, are killed.

NOTE 2 Intermediate level disinfection is when *Mycobacterium tuberculosis*, most viruses and fungi are killed, but not necessarily bacterial spores.

NOTE 3 Low-level disinfection is when most bacteria, some viruses and some fungi are killed, but the complete absence of resistant micro-organisms such as tubercle bacilli or bacterial spores cannot be relied on.

3.1.15

disposal

approved deposit, discharge, dumping, placing, or release of any waste material into or on air, land or water in an approved, specified facility, e.g. near surface or geological repository, or the approved direct discharge of effluents into the environment without the intention of retrieval

3.1.16

genotoxic

substance that is capable of interacting directly with genetic material, causing DNA damage that can be assayed for analysis and DNA damage that can be passed on to off-spring

3.1.17

'green' procurement

selection of products and services that minimizes the impact of the products and services on the environment

3.1.18

ground water

water that occupies pores in the soil and cavities and spaces found in the rocks which are situated in the saturated zone of the profile by rising from a deep magmatic source or by the infiltration of rainfall

SANS 10248-1:2008

Edition 1

3.1.19 handling

functions associated with the movement of healthcare waste, including storage, treatment and ultimate disposal, by the use of manual systems and automated systems

3.1.20 hazard

intrinsic potential property or ability of any agent, equipment, material, or process to cause harm

NOTE Harm is an injury or damage to the health of humans or to the environment (or both).

3.1.21 healthcare facility

place or site where professional health services are dispensed to human or animal patients or where biological research is carried out, e.g. laboratories, and includes, *inter alia*, hospitals, clinics, laboratories, rehabilitation centres, sick bays, old age homes, free-standing operating theatres, day units, mobile and stationary clinics, and field stations where biomedical samples are taken

3.1.22 incineration

controlled burning of solid, liquid, or gaseous combustible wastes to produce gases and residues that contain little or no combustible material

3.1.23 micro-organism

any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material

3.1.24 monitoring

continuous or non-continuous measurement of a concentration or other parameters for purposes of assessment or control of environmental quality or exposure and the interpretation of such measurements

3.1.25 radiotherapy

use of ionizing radiation to treat disease

3.1.26 recycling

extraction and recovery of material from scrap or other discarded material that can be reprocessed to manufacture a new product

3.1.27 residue

material, such as ash or slag, that remains after combustion or treatment of wastes, or materials extracted from a liquid or gas stream

3.1.28 risk

probability that a hazard will cause harm, and the severity of that harm

3.1.29 segregation

systematic separation of healthcare waste into designated categories

3.1.30

sewage

community's liquid waste, that is carried off in sewers and comprises a combination of the liquid or water-carried wastes from domestic, municipal, and industrial premises

3.1.31

sewer

system for the collection and transportation of sewage, including conduits, pipes, and pumping stations

3.1.32

sharps

items such as needles, syringes, blades or clinical glass, that are capable of causing cuts, abrasions or puncture wounds

3.1.33

sterilization

reduction of more than 99,9999 % or $6 \log_{10}$ of the micro-organisms present by means of physical, chemical, or mechanical methods, or by irradiation

3.1.34

storage

placement of waste in a suitable location or facility where isolation, environmental and health protection, and human control (e.g. monitoring for radioactivity and limitation of access) are provided with the intention that the waste will be subsequently retrieved for treatment or disposal (or both) (or clearance of radioactive waste)

3.1.35

treatment

any method, technique or process for altering the biological, chemical, or physical characteristics of the waste in order to reduce the hazards it presents and to facilitate its disposal by volume reduction, disinfection, neutralization, or other change of form

3.1.36

waste

undesirable or superfluous by-product, emission, residue or remainder of any process or activity, any matter, gaseous, liquid or solid or any combination thereof, which

- a) is discarded by any person;
- b) is accumulated and stored by any person with the purpose of eventually discarding it with or without prior treatment connected with the discarding thereof; or
- c) is stored by any person with the purpose of recycling, reusing or extracting a usable product from such matter

3.1.36.1

anatomical waste

pathological waste

waste that contains tissues, organs, body parts, blood and body fluids from patients, fetuses and animal carcasses, but excludes teeth and hair

NOTE 1 Anatomical waste is considered as a subcategory of infectious waste even though it can also include healthy body parts.

NOTE 2 Blood and body fluids from healthy individuals do not fall under this category.

NOTE 3 Animal carcasses generated by the public are not covered by this definition.

3.1.36.2

chemical waste

solid, liquid and gaseous products that are to be discarded and that contain dangerous or polluting chemicals that pose a threat to humans, animals or the environment, when improperly disposed of

3.1.36.3

cytotoxic waste

waste that is toxic to cells and that can lead to cell death

3.1.36.4

genotoxic waste

waste capable of interacting with living cells and causing genetic damage

3.1.36.5

hazardous waste

waste that can, by circumstances of use, quantity, concentration or inherent physical, chemical or toxicological characteristics, have a significant adverse affect on public health and the environment when improperly treated, stored, transported or disposed of

3.1.36.6

healthcare general waste

the portion of waste that poses a minimum degree of risk to human health and the environment, i.e. from administrative and housekeeping activities, e.g. paper, pens, flowers, food packaging, plastics cooldrink bottles, old mops, builders' rubble and garden waste

3.1.36.7

healthcare risk waste

human and animal anatomical waste, infectious human and animal waste, sharps, chemical waste, pharmaceutical waste and radioactive waste generated by healthcare professionals, healthcare facilities and other non-healthcare professionals, e.g. tattooists and taxidermists

NOTE Healthcare risk waste is a subcategory of hazardous waste.

3.1.36.8

infectious non-anatomical waste

waste that contains or is suspected to contain pathogens, bacteria, viruses, parasites or fungi in sufficient concentrations or quantities to cause disease in susceptible hosts

3.1.36.9

pharmaceutical waste

unused medicines, medications and residues of medicines that are no longer usable as medication

3.1.36.10

radioactive waste

liquid, solid or gaseous materials that contain, or are contaminated with, radionuclides at concentrations or activities greater than the clearance levels and for which no use is foreseen

3.1.37

waste generator

any person, organization or facility engaged in activities that generate waste

3.1.38

waste management

all activities, administrative and operational, involved in the handling, treatment, conditioning, storage, and disposal of waste (including transportation)

3.1.39

waste package

product which includes the waste form, waste container(s), and any internal barriers (e.g. absorbing materials or liners), prepared in accordance with the requirements for handling, transportation, storage, and disposal

3.2 Abbreviations

3.2.1 DEHP Di(2-ethylhexyl)phthalate

3.2.2 EVA ethyl vinyl acetate

3.2.3 HR Hazard Rating

3.2.4 IV intravenous

3.2.5 NCS Natural Colour System ®

3.2.6 PVC poly(vinyl chloride)

3.2.7 Sv sievert (1 Sv = 1 J/kg)

4 Requirements

4.1 Management requirements

4.1.1 The chief executive officer (see 3.1.6) shall retain overall responsibility for the management of healthcare risk waste in accordance with the relevant requirements and regulations of the current relevant national legislation (see annex A), or any other regulatory requirements of the relevant provincial and local governments.

4.1.2 The CEO of a healthcare facility

- a) may assign responsibilities for the management of healthcare risk waste,
- b) shall adopt a documented waste management policy,
- c) shall approve the implementation plan developed by the waste management team (see 4.2),
- d) shall monitor and review the implementation of the waste management plan,
- e) shall provide sufficient resources for onsite storage facilities, if necessary, and the operation of the facilities in accordance with the current relevant national legislation (see annex A),
- f) shall be responsible for the compliance of on-site treatment facilities with the current relevant national legislation (see annex A), and
- g) shall provide an environmental management policy, where applicable, in accordance with the current relevant national legislation (see annex A).

4.2 Requirements for the waste management team

4.2.1 General

4.2.1.1 The waste management team shall be assigned in accordance with 4.1.2(a) and, depending on the type of healthcare facility, may comprise of the following key members,

- a) a waste management officer;
- b) heads of departments;
- c) an infection control officer;
- d) a chief pharmacist;
- e) a radiation officer;
- f) a senior nursing manager;
- g) a health and safety manager;

NOTE A nominated health and safety representative can be represented on the waste management team. If a health and safety manager has been appointed to oversee two or more health and safety representatives at a healthcare facility, then the health and safety manager can be part of the waste management team.

- h) a maintenance engineer (where possible) or a maintenance manager;
- i) a financial manager;
- j) a procurement manager; and
- k) a waste management contractor when applicable and when required as an advisor in meetings.

NOTE 1 This is not a complete list of the waste management team. The waste management team can also include the cleaning contractor, regional managers or union representatives.

NOTE 2 An environmental health practitioner can monitor incidences that can result in injuries.

4.2.1.2 Members of the waste management team can also hold other positions at the healthcare facility and perform their waste management team responsibilities on an add-on basis.

4.2.1.3 The waste management team shall include the functions of all departments when developing the waste management plan as illustrated in the flow diagram in figure 1.

4.2.1.4 The person responsible for an area or department shall ensure that the healthcare risk waste is managed in that area.

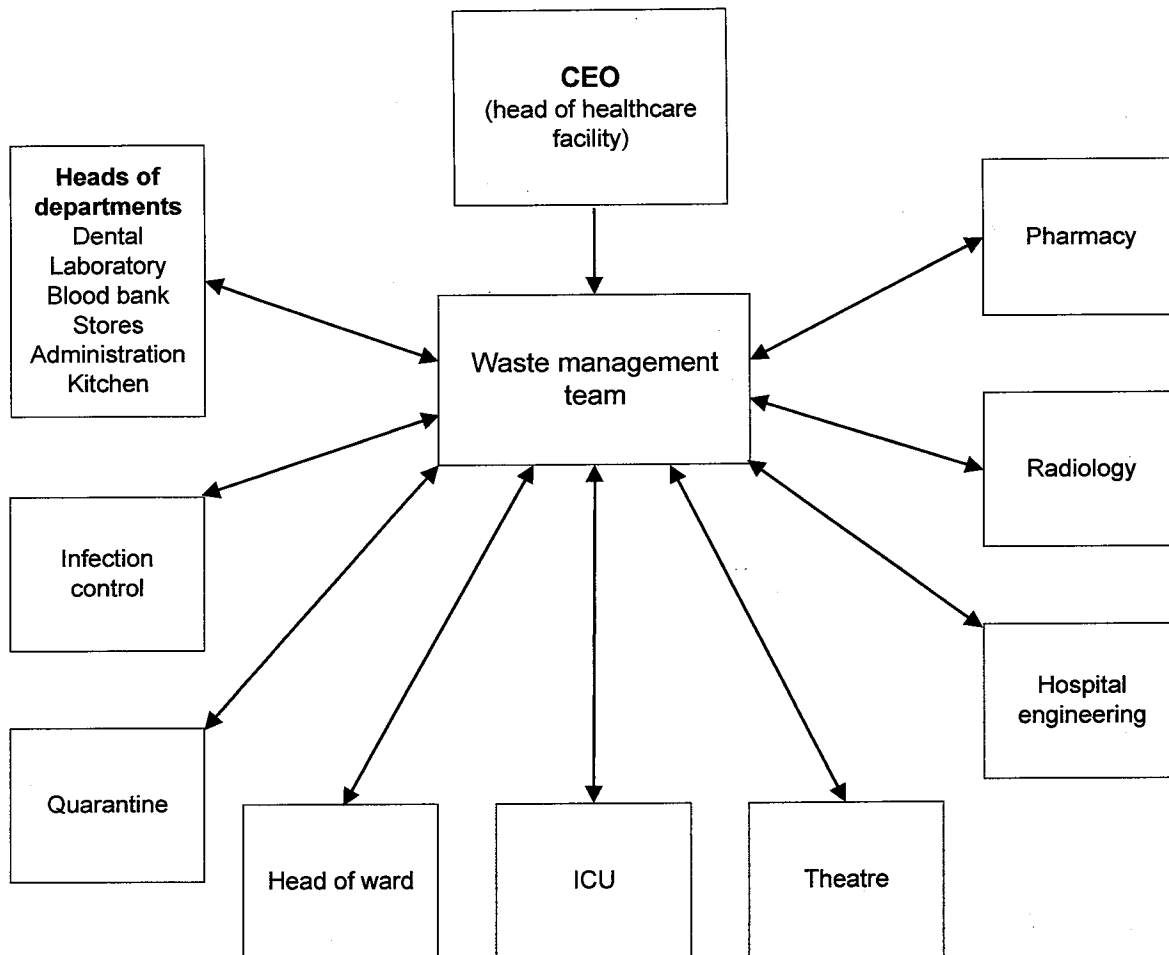


Figure 1 — Example of functions in a healthcare facility

4.2.2 Waste management officer

The waste management officer shall:

- a) be responsible for the development of a written waste management plan that defines the duties of all staff members in respect of handling healthcare risk waste;
- b) be responsible for the day to day operation, monitoring and implementation of the waste management plan;
- c) be responsible for the control of internal collection and transportation of waste;
- d) monitor and coordinate the staff assigned to containerize, collect, transport and store the healthcare risk waste within the healthcare facility;
- e) ensure that healthcare general waste (see 3.1.36.6) destined for recycling is stored in a separate area or storeroom;
- f) ensure that the waste storage points are managed acceptably to prevent unauthorized dumping;
- g) liaise with the other members of the waste management team to minimize any healthcare risk

waste disposal anomalies and ensure compliance with the waste management plan;

- h) monitor the treatment and disposal of the healthcare risk waste on-site, where applicable;
- i) monitor the collection of the healthcare risk waste by the waste management contractor in accordance with the waste management contract (see annex B) and the waste management plan; and
- j) maintain records of all data produced from consignment notes and any other sources.

4.2.3 Heads of departments

The heads of departments shall manage the generation of healthcare risk waste in their departments, including waste avoidance, segregation, containerization, storage and treatment or disposal (or both). They shall also ensure that:

- a) the doctors, nurses, clinical and non-clinical professional personnel
 - 1) are trained in the segregation and storage procedures of waste, and
 - 2) comply with the waste management plan;
- b) key personnel are trained in the segregation, containerization, storage and internal transportation of healthcare risk waste;
- c) workers are adequately supervised with regard to all operations, including the safe handling of healthcare risk waste; and
- d) any non-compliance of procedures are noted and resolved with the assistance of the waste management officer.

4.2.4 Infection control officer

The infection control officer shall advise the waste management team on

- a) infection control,
- b) the handling of infectious waste,
- c) the health and safety policy, and
- d) the treatment and disposal of healthcare risk waste.

4.2.5 Chief pharmacist

The chief pharmacist shall:

- a) ensure the minimization of pharmaceutical waste;
- b) advise the waste management team on pharmaceutical waste treatment or disposal (or both);
- c) monitor and coordinate the pharmaceutical waste generation, treatment or disposal; and
- d) train staff that are involved in pharmaceutical waste disposal.

4.2.6 Radiation officer

The radiation officer shall:

- a) be appointed by the CEO in accordance with the relevant requirements and regulations of the current relevant national legislation (see annex A);
- b) be responsible for the minimization of radioactive waste by storing short half-life radioactive waste until decayed to a surface dose rate not exceeding 5 $\mu\text{Sv/h}$;
- c) advise the waste management team on the segregation and disposal of radioactive waste;
- d) coordinate the monitoring of radioactive waste production and treatment or disposal; and
- e) be responsible for the training of staff involved in radioactive waste treatment or disposal (or both).

4.2.7 Senior nursing manager

The senior nursing manager shall ensure that nursing staff, assistants, attendants and ancillary staff are trained in the correct procedures for segregation, containerization, storage and internal transportation of healthcare risk waste.

4.2.8 Health and safety manager

The health and safety manager shall:

- a) report any injuries to employees during activities related to the management of healthcare risk waste (see 5.8.3);
- b) investigate and record any complaints regarding health and safety in accordance with the requirements and regulations of the current relevant national legislation (see annex A);
- c) review the effectiveness of the health and safety measures;
- d) liaise with the waste management team to identify potential hazards; and
- e) maintain records of all incidents that contravene operating procedures.

4.2.9 Maintenance engineer or maintenance manager

The maintenance engineer or maintenance manager shall be responsible for

- a) the instalment and maintenance of waste storage facilities, equipment used in the handling of the waste, and on-site waste treatment or disposal facilities,
- b) the training of staff in the operation and maintenance of such facilities and equipment, and
- c) keeping records of the maintenance of the facilities and equipment, and for training of the relevant staff members.

4.2.10 Financial manager

The financial manager shall ensure that there is a budget for the management of healthcare risk waste.

5 The waste management plan

5.1 General

5.1.1 The waste management team shall make an assessment of all the healthcare risk waste generated in the healthcare facility before the development of a waste management plan. The assessment shall include estimates of any future changes in the growth, or designation, of the

healthcare facility or its departments. Data from the survey shall form the basis on which the waste management plan shall be developed.

NOTE It is recommended that the waste management team consider the options and procedures given in the *Self-assessment manual for proper management of medical wastes* (see bibliography) when starting on the development of a waste management plan.

5.1.2 The waste management team shall establish and maintain a documented waste management plan in accordance with the relevant requirements and regulations of the current relevant national legislation (see annex A). The waste management plan shall include documents for all the processes in the healthcare facility (see 5.2.1).

5.1.3 An implementation plan shall form part of the waste management plan.

5.1.4 The waste management team shall ensure that there are written contingency procedures in the event of failure of any aspect of the waste management plan and that trained personnel are aware of the action to be taken.

5.1.5 The waste management team shall be responsible for the constant review and update of the waste management plan to assess opportunities for improvements and to ensure compliance with regulations.

5.2 Documentation requirements

5.2.1 Documents

The documents to be used in the healthcare facility shall include:

- a) work instructions and work procedures that are documented, implemented and maintained;
- b) work instructions and work procedures for training that are developed in a comprehensible format;
- c) quality control procedures;
- d) a document for *pro forma* service level agreements between the different departments;
- e) applicable documents that are available at the point of use;
- f) operating manuals for all equipment;
- g) safety instructions and precautions for the handling and storage of all healthcare risk waste;
- h) an emergency response policy and strategy to deal with spills of infectious and chemical wastes (see 10.1);
- i) non-compliant procedures and the appropriate corrective actions to be taken;
- j) a document on the conduct and behaviour of staff and non-staff members (see 5.6.3);
- k) a document that describes the retention of documents as proof of the proper treatment, destruction and disposal of the healthcare risk waste by the waste management contractor; and
- l) a document that describes record keeping for waste management.

5.2.2 Document control

The waste management team shall establish a procedure for the control of **all** documents related to the approved waste management plan. The controls shall include the following:

- a) that all documents are first reviewed and approved for adequacy before being issued;
- b) the establishment of a suitable identification system for all documents;
- c) the review, update (when necessary) and re-approval of documents every three years;
- d) the establishment of a master list of all controlled documents that indicates the location of the documents and their revision status;
- e) that obsolete documents be withdrawn and replaced with current versions;
- f) that records be controlled in accordance with the policy of the healthcare facility; and
- g) the retention of all documentation and certificates in terms of the relevant requirements and regulations of the current relevant national legislation (see annex A) and the relevant regulatory requirements related to labour issues.

NOTE See annex C for examples of documents.

5.3 Contractual commitments

5.3.1 Contracts for the treatment and disposal of the healthcare risk waste (see annex B) shall be entered into **only** when the waste management contractor discloses a license or permit authorized by the relevant authority for the treatment or disposal (or both) of each category of healthcare risk waste in accordance with the relevant requirements and regulations of the current relevant national legislation (see annex A).

5.3.2 The healthcare facility shall be responsible for the healthcare risk waste from generation to its final disposal in accordance with the relevant requirements and regulations of the current relevant national legislation (see annex A), even when a contract has been agreed to with a waste management contractor for the treatment and disposal of this waste.

5.3.3 The healthcare facility shall maintain documented evidence of monitoring the waste management contractor (see 5.2.1(k)), e.g. that destruction documents are completed and correctly signed-off (see also 9.1.2, 9.3.1.8 and 11.6.2).

5.3.4 The requirements to be included in the contractual agreement between the healthcare facility and the waste management contractor are given in annex B.

5.4 Work procedures and work instructions

5.4.1 The work procedures and work instructions for the management of healthcare risk waste shall be:

- a) in a format that is easy to read and that is comprehensible to operators; and
- b) posted at work places and at the point of use.

5.4.2 Work procedures and work instructions shall be established for at least the following:

- a) the identification of the healthcare risk waste category in accordance with 6.1 and table 1;

SANS 10248-1:2008
Edition 1

- b) the segregation of the healthcare risk waste into an appropriate colour-coded container (see 6.3 and table 1);
- c) training in the work procedures and work instructions (see 5.7);
- d) cleaning and disinfection;
- e) the correct use of all facilities, equipment and personal protective equipment;
- f) the storage of the healthcare risk waste at the point of generation until its collection;
- g) the transportation of the containerized healthcare risk waste for storage (see clause 9);
- h) the transportation of the healthcare risk waste for on-site treatment;
- i) the on-site treatment of the healthcare risk waste;
- j) the classification and final disposal of the residue from the treated healthcare risk waste in accordance with the relevant requirements and regulations of the current relevant national legislation (see annex A);
- k) the control and monitoring of processes in each department to achieve the specified cleanliness and infection control;
- l) rules on leaving the work area, and for working hours and break times; and
- m) visual warnings and details on hazardous healthcare material, dangerous areas and technical facilities that can create hazards.

5.5 Inspection and quality control

Each department shall provide documentation that verifies

- a) the categories of healthcare risk waste generated (see table 1),
- b) the number and sizes of containers of each category of healthcare risk waste generated in a specific time period,
- c) the date of collection,
- d) the authorized collector and proposed final point of treatment or disposal (or both),
- e) any deviations from the standard procedure,
- f) any corrective actions taken, and
- g) a record of treatment and disposal by the waste management contractor.

NOTE The recording of treatment and disposal at departmental level can be required by the waste management plan.

5.6 Health and safety policy

5.6.1 The waste management plan shall include the health and safety policy, and shall be issued and communicated to all employees.

5.6.2 The health and safety policy shall include recommendations for a medical examination or check-up, and a policy on immunization for employees in contact with, or handling, healthcare risk waste.

NOTE 1 It is recommended that employees be offered counselling and appropriate immunization for certain

diseases, e.g. hepatitis B and tetanus. Counselling and treatment should also be offered to employees after occupational exposure to HIV and AIDS.

NOTE 2 It is recommended that employees who decline immunization, or who do not seroconvert, be advised in writing about the occupational risk associated with the work environment.

5.6.3 The health and safety policy shall be supplemented and supported by house rules which shall govern the conduct of personnel at the healthcare facility, non-company personnel, and the personnel of the waste management contractors (see annex B).

5.6.4 The health and safety policy shall be aimed at the safety and well-being of all employees, visitors and the public. The policy shall also ensure that all risks are considered and that the appropriate action is taken by the waste management officer to prevent the infection and contamination of the environment with healthcare risk waste.

5.6.5 The health and safety policy shall comply with all the relevant requirements and regulations of the current relevant national legislation that relate to air pollution, water pollution, soil pollution, occupational health and safety, and public health (see annex A).

5.7 Training

5.7.1 Training shall be provided to all employees at the beginning of employment, all contract workers that might be exposed to healthcare risk waste, and when new tasks or equipment are introduced. The training shall cover at least the following:

- a) the nature of the work;
- b) the chain of command, including the name(s) of the person(s) responsible for the work area(s);
- c) the safe handling of hazardous waste;
- d) the contents of the Material Safety Data Sheets (MSDSs);
- e) the meaning of the specific hazard risk warnings (R-phrases) and safety advices (S-phrases) likely to be found on the MSDSs;

NOTE SANS 10265 can be consulted regarding the format of an MSDS and the meanings of the R-phrases and S-phrases.

- f) the use of protective clothing;
- g) disposal procedures; and
- h) information on the health hazards associated with the work.

5.7.2 The training shall be repeated, refreshed or updated at least once a year.

5.7.3 A sufficient number of employees shall receive training to cover for leave periods, absences due to illness, and public holidays.

5.7.4 An attendance register should be kept and signed by each employee at each training session.

5.8 Workplace hygiene

5.8.1 Employees shall not eat, drink or smoke in areas where healthcare risk waste is handled and stored. "No smoking" signs shall be displayed and obeyed at all times.

SANS 10248-1:2008

Edition 1

5.8.2 Separate areas shall be designated or provided for eating, drinking and smoking, in accordance with the relevant requirements and regulations of the current relevant national legislation (see annex A).

5.8.3 All injuries, including minor traumas, shall receive immediate medical attention and shall be reported to the health and safety representative in accordance with the relevant requirements and regulations of the current relevant national legislation (see annex A). Records of all reports shall be kept.

5.8.4 A regular supply of clean overalls, protective clothing, gloves and footwear, or other appropriate safety equipment that is specific for the work activities, shall be provided.

5.8.5 Work clothing shall be washed between uses by a laundry facility equipped to process clothing from healthcare facilities.

5.8.6 Employees that are in contact with or handle all hazardous healthcare risk waste shall also be provided with suitable gloves, aprons and, where necessary, face masks or breathing apparatus.

5.8.7 Employees working with hazardous healthcare risk waste shall not enter clinical areas or recreation or eating facilities without the removal of protective clothing.

5.8.8 When leaving "clean" areas, employees shall wash and don clean overalls or protective clothing upon returning to the "clean" areas.

5.8.9 Employees at managerial level, and visitors, shall wear the appropriate protective clothing when entering areas allocated for the handling of hazardous healthcare risk waste.

5.8.10 Personal protective equipment and facilities shall be kept clean and in good condition.

5.8.11 Hand-wash basins and, where applicable, showers with hot and cold water and soap or shampoo shall be provided.

5.8.12 The lockers provided to store personal clothing and personal items shall be situated away from work areas. The lockers shall not be used to store work clothing and personal protective equipment.

5.8.13 An emergency shower or eye-wash facility shall be provided in the washroom area and where chemicals are stored or handled.

6 Identification, classification, segregation, collection and minimization of healthcare waste

6.1 Identification

6.1.1 The management of healthcare risk waste shall start with the correct identification of the waste, followed by classification, segregation, collection and minimization. The generators of waste shall be responsible for the identification and segregation of the waste.

6.1.2 Healthcare waste is grouped into healthcare risk waste and healthcare general waste and categorized as follows:

- a) **healthcare risk waste categories:** infectious waste, anatomical (pathological) waste, sharps, chemical and pharmaceutical waste, heavy metals, pressurized containers and radioactive waste; and

b) **healthcare general waste categories:** packaging material, kitchen waste (domestic waste), office waste and building demolition waste, waste from patients (e.g. fruit juice bottles and magazines), non-clinical glass, non-infectious non-anatomical waste (e.g. paper tissues), disposable curtains, extracted teeth, nail clippings, hair and decontaminated waste, and garden and park waste.

6.1.3 For traceability and treatment purposes the waste shall be identified in accordance with 6.1.2 and shall be correctly labelled.

6.2 Classification (see annex D)

All healthcare risk waste shall be classified in accordance with SANS 10228, as expanded on in the relevant requirements and regulations of the current relevant national legislation (see annex A). The healthcare risk waste shall also be classified in accordance with the hazard and risk involved.

6.3 Waste segregation

6.3.1 The waste shall be segregated at the point of generation and shall be containerized to minimize the risk of contamination or pollution to the environment and humans.

6.3.2 Employees shall be trained in the correct identification and segregation of the waste (see flow diagram in figure 2).

6.4 Collection

The healthcare risk waste shall be collected at the point of generation (where applicable) and shall be the first step in the removal of the waste to its final disposal point.

6.5 Waste minimization

Careful pre-planning can minimize the amount of healthcare risk waste generated by a healthcare facility. Effective procurement and stock management, recycling where possible, and resource recovery should be considered as part of the management of waste.

NOTE See annex E for information on 'green' procurement.

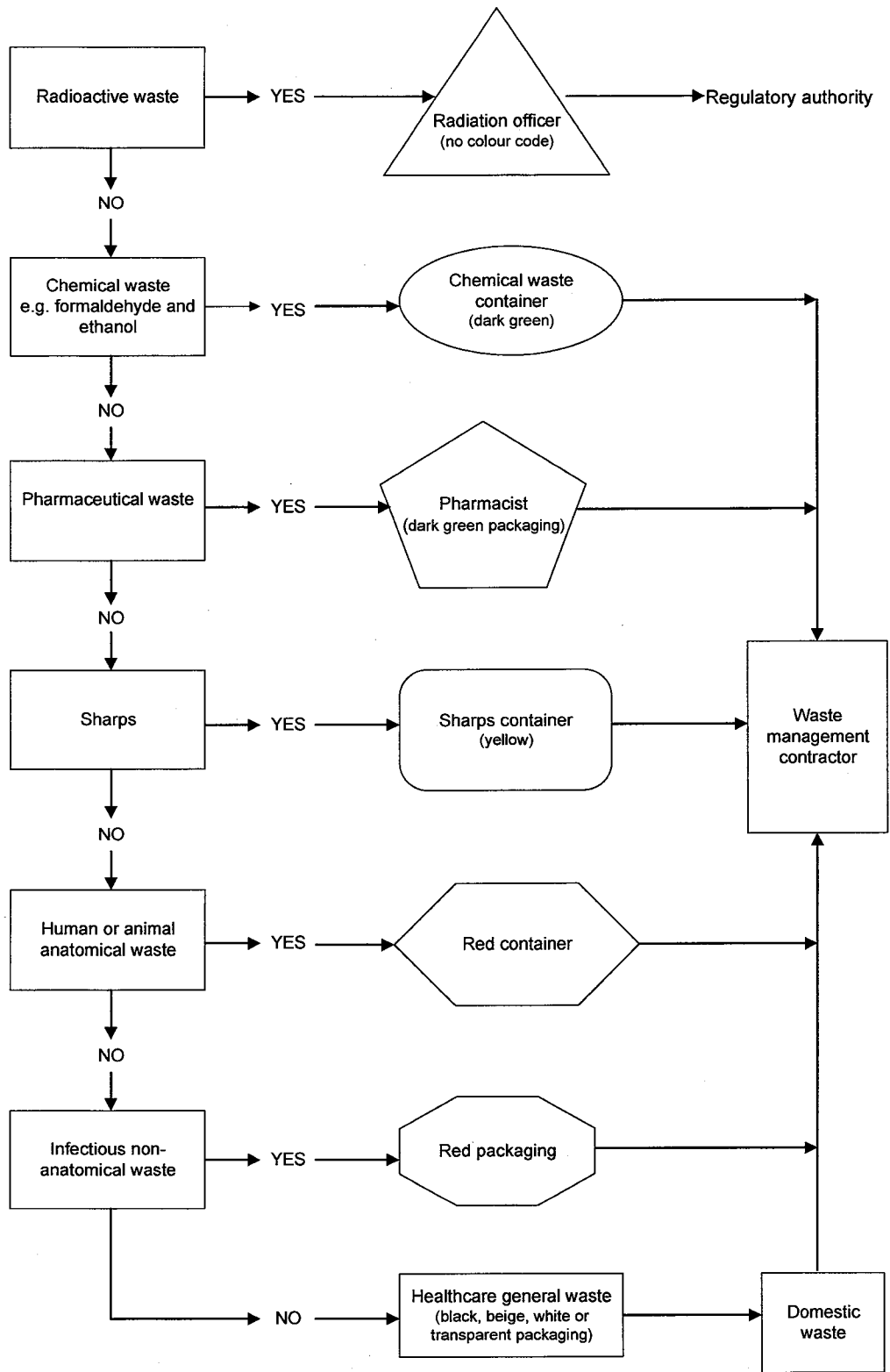


Figure 2 — Healthcare risk waste flow diagram

7 Packaging

7.1 Packaging requirements for healthcare general waste

7.1.1 Solid healthcare general waste shall be placed in a colour-coded waste container in accordance with table 1.

7.1.2 A plastics bag used for the containment of healthcare general waste shall not tear easily during handling and transportation.

7.1.3 The waste containers shall be filled in accordance with the relevant requirements and regulations of the current relevant national legislation (see annex A) and shall be securely closed to prevent spillage of the contents and access by scavengers or vermin.

NOTE Arrangements can be made with a waste removal service for high-density materials such as small amounts of building rubble and garden refuse, e.g. by the provision of on-site collecting bins.

7.2 Packaging requirements for healthcare risk waste

7.2.1 Plastics bags used as stand-alone containers shall have a thickness of 80 µm or more.

7.2.2 Plastics bags used as liners which form an integral part of a rigid container shall have a thickness of 60 µm or more.

7.2.3 When transported, all healthcare risk waste shall be packed and labelled in accordance with SANS 10229-1.

7.2.4 The lettering on the label shall be of a size, style and layout that is clearly legible. The colour of the surface area immediately surrounding the label shall contrast with the background of the label.

7.3 Colour coding of packaging

7.3.1 The packaging for healthcare risk waste shall be clearly marked with the appropriate colour code and the appropriate international hazard label(s) illustrated in annex F.

7.3.2 Table 1 gives the internationally accepted categories, sub-categories, colour coding, and labelling protocol for healthcare waste.

NOTE A colour coding system is used for ease of identification for the different categories.

Table 1 — Healthcare waste categories, colour coding and international hazard label

1	2	3
Waste	Waste sub-category	Colour coding and international hazard label ^a
^b Human or animal anatomical waste	Infectious human anatomical	RED and the appropriate international infectious hazard label
	Infectious animal anatomical	ORANGE and the appropriate international infectious hazard label
	Non-infectious animal anatomical	BLUE
^b Infectious non-anatomical waste	None	RED and the appropriate international infectious hazard label
Sharps	None	YELLOW , the words " DANGER CONTAMINATED SHARPS " and the appropriate international infectious hazard label
Chemical waste including pharmaceutical waste	Chemical or pharmaceutical	DARK GREEN and the appropriate international hazard label
	Cytotoxic pharmaceutical	DARK GREEN and the cytotoxic hazard label (see figure 3)
Radioactive waste	None	No colour coding – only the appropriate international radiation hazard label
General waste		No hazard label ^c
^a See annex F for international hazard labels. ^b Chemical or radioactive solutions that contain human or animal anatomical and infectious non-anatomical wastes are considered as chemical waste or radioactive waste, respectively. ^c Black, beige, white or transparent packaging can be used.		

7.4 Packaging for infectious waste (excluding sharps)

7.4.1 Packaging for infectious waste shall be made from an impermeable, leak-proof material and shall be compatible with the envisaged treatment of the waste.

7.4.2 Packaging for infectious waste shall be filled to three-quarters capacity of the container and shall be securely closed.

7.4.3 Plastics bags shall be closed by means of non-PVC plastics ties, non-PVC plastics sealing tags of the self-locking type, or heat sealers purpose-made for healthcare risk waste. Plastics bags shall **not** be closed by means of stapling.

7.4.4 All category A waste, as indicated in SANS 10228 (e.g. contaminated with viral haemorrhagic fevers), shall be handled in accordance with procedures of the healthcare facility. The waste shall be placed into a double-layered plastics bag colour-coded in accordance with table 1 and shall be sealed (see 7.4.3). The sealed bag shall then be placed into a rigid disposable container colour-coded and labelled in accordance with table 1.

7.5 Packaging for sharps

7.5.1 A sharps container shall be used for the collection of all sharps (see 3.1.32).

7.5.2 All sharps containers shall be:

- a) manufactured in accordance with SANS 452;
- b) rigid, puncture-proof, tamper-proof and clearly marked in accordance with 7.2.3, 7.2.4 and table 1; and
- c) constructed from a material and in a manner that safely retains the sharps and any residual liquids from syringes (e.g. high-density polypropylene).

7.5.3 The lid of a sharps container shall be such that when sealed it cannot be released without excessive force. In the case of reusable sharps containers, the lid shall only be opened by means of an automated process or a process that prevents the risk of needle-stick injuries and contamination to the employees at the waste disposal facility.

7.5.4 The sharps container available in each department shall be appropriate for the type of work (e.g. a large sharps container where trocars are used).

7.5.5 Consideration can be given to the installation of needle destructors (incinerators) particularly when sharps waste disposal facilities are not optimal. This option shall **only** be applicable on the availability of a safe disposal system for the residue after incineration, and provided that the needle incinerator shall be used and maintained efficiently.

7.6 Packaging for chemical waste

7.6.1 General

7.6.1.1 Chemical waste intended for transportation outside a healthcare facility shall be classified in accordance with SANS 10228 and shall be packaged in accordance with SANS 10229-1 or SANS 10233.

7.6.1.2 Chemical waste shall first be sorted into the different hazard classes (see annex D) and then divided into chemical, pharmaceutical or cytotoxic waste, as applicable. Hazardous chemical waste of different classes shall not be mixed.

7.6.1.3 The packaging shall be clearly colour-coded dark green (see table 1) and marked in accordance with 7.2.3 and 7.2.4.

7.6.1.4 Chemical waste may be placed in empty containers that originally contained the same type of chemical, provided that the original label is removed or clearly defaced.

7.6.2 Packaging for waste aerosol dispensers and gas cylinders of class 2

7.6.2.1 Waste aerosol dispensers

Waste aerosol dispensers shall:

- a) be stored in black plastics bags and shall be clearly marked "**Waste aerosol dispensers**" to distinguish from general waste;
- b) be itemised separately in a plastics bag for disposal via landfill or for recovery at a specialized facility; and
- c) not be disposed of by incineration.

7.6.2.2 Gas cylinders

7.6.2.2.1 Empty gas cylinders shall not be disposed of as healthcare general waste or healthcare risk waste or in an alternative treatment facility, and shall not be incinerated.

7.6.2.2.2 Empty gas cylinders shall be returned to the supplier for reuse, where appropriate.

7.6.3 Packaging for waste flammable liquids of class 3

7.6.3.1 Chlorinated and non-chlorinated solvents shall be segregated and stored in separate waste containers.

7.6.3.2 A waste flammable liquid can be stored in a metal or a high-density plastics container, or drum, that can be sealed with a screw cap lid. An alternative that might be acceptable for audit purposes would be to store the waste solvents in empty containers from which they were supplied (see 7.6.1.4).

7.6.3.3 Each container or drum shall:

- a) be marked "CHLORINATED ORGANIC SOLVENT WASTE" or "ORGANIC SOLVENT WASTE";
- b) be colour-coded dark green in accordance with table 1;
- c) bear the appropriate international hazard label for flammable liquids of class 3 (see annex F); and
- d) have, where necessary, a bold warning "**HIGHLY FLAMMABLE**" or "**FLAMMABLE**" depicted.

7.6.4 Packaging for waste oxidizing substances and organic peroxides of class 5

7.6.4.1 Waste oxidizing substances (see division 5.1 in annex D) and organic peroxides (see division 5.2 in annex D) shall be kept apart and shall also be segregated from other wastes.

7.6.4.2 These types of waste (see 7.6.4.1) shall be stored in plastic-lined metal drums, or high-density plastics drums, and shall be fitted with tamper-proof sealable lids.

7.6.4.3 A container with division 5.1 waste shall be clearly marked "OXIDIZING CHEMICAL WASTE" and shall bear the appropriate international hazard label for oxidizers of division 5.1 (see annex F).

7.6.4.4 A container with division 5.2 waste shall be clearly marked "ORGANIC PEROXIDE WASTE" and shall bear the appropriate international hazard label for organic peroxides (see annex F).

7.6.5 Packaging for waste toxic substances of class 6, division 6.1

7.6.5.1 Waste toxic substances shall be segregated and each type of toxic waste shall be stored in a separate container.

7.6.5.2 The containers shall be made of metal or high-density plastic and shall be sealed with a screw cap lid or a tamper-proof lid.

7.6.5.3 Each container shall:

- a) be clearly marked to indicate the toxic chemical waste inside;
- b) be colour-coded dark green in accordance with table 1; and
- c) bear the appropriate international hazard label for toxic substances of division 6.1 (see annex F).

7.6.5.4 Empty containers in which extremely toxic chemicals are supplied shall not be stored for future use as waste storage containers.

7.6.6 Packaging for pharmaceutical waste

WARNING! SPECIAL PRECAUTIONS ARE TO BE TAKEN TO PREVENT THE THEFT AND ILLEGAL DISTRIBUTION OF PHARMACEUTICAL WASTE.

7.6.6.1 The containers for liquid pharmaceutical waste shall:

- a) be made of metal or high-density plastic and shall be sealed with a screw cap lid or a tamper-proof lid;
- b) be clearly marked "PHARMACEUTICAL WASTE – LIQUID";
- c) be colour-coded dark green in accordance with table 1; and
- d) bear the appropriate international hazard label for toxic substances of division 6.1 (see annex F).

7.6.6.2 When the liquid pharmaceutical waste has a subsidiary risk of "flammability", the appropriate international hazard label for flammable liquids of class 3 shall also be affixed to the waste container.

7.6.6.3 Solid pharmaceutical waste shall be stored in double layer plastics bags which shall:

- a) be colour-coded dark green in accordance with table 1;
- b) be clearly marked "PHARMACEUTICAL WASTE – SOLID"; and
- c) bear the appropriate international hazard label for toxic substances of division 6.1 (see annex F).

7.6.6.4 The plastics bags for solid pharmaceutical waste shall be securely sealed by means of non-PVC plastics ties, steel-wire, non-PVC plastics sealing tags of the self-locking type, or heat sealers purpose-made for healthcare risk waste.

7.6.7 Packaging for cytotoxic and genotoxic waste

7.6.7.1 Cytotoxic waste can be generated from several sources that include the following:

- a) contaminated material from drug preparation and administration (e.g. needles, gauges, vials and packaging);



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

**GENERAL ETHICAL GUIDELINES FOR
HEALTH RESEARCHERS**

BOOKLET 13

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcsa@hpcsa.co.za

Website: <http://www.hpcsa.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care professional requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practice as a health care professional is a moral enterprise. In this spirit the Health Professions Council of South Africa presents the following ethical guidelines.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1. PREAMBLE	1
2. INTRODUCTION	1
3. ETHICAL GUIDELINES IN HEALTH RESEARCH.....	2
4. BASIC ETHICAL PRINCIPLES IN HEALTH RESEARCH.....	2
5. THE SOCIAL VALUE OF RESEARCH	3
6. DUTIES TO RESEARCH PARTICIPANTS	3
7. DUTIES TO RESEARCH COLLEAGUES AND OTHER PROFESSIONALS.....	8
8. DUTIES TO HEALTH RESEARCHERS THEMSELVES.....	8
9. DUTIES TO SOCIETY	9
10. DUTIES TO THE HEALTH CARE PROFESSION	10
11. DUTIES TO ANIMALS	11
12. DUTIES TO THE ENVIRONMENT.....	11
13. DATA AND SPECIMEN STORAGE AND TRANSFER.....	11

GENERAL ETHICAL GUIDELINES FOR HEALTH RESEARCHERS

1. PREAMBLE

Biomedical research has made spectacular strides during the past century. That medical research has increased the well being of humans in much of the world is without doubt but the power to save human lives and ameliorate disease has also raised concerns about how this is achieved and how its fruits will be distributed. South Africa with its scientific expertise, advanced infrastructure, developing country burden of disease and large number of vulnerable populations provides fertile ground for research. Moreover the country is still recovering from its many years under apartheid. Hence the misuse of power in research cannot be ignored. The following guidelines should serve as a reference to research institutions, organisation and researchers registered with the HPCSA

2. INTRODUCTION

- 2.1 Being registered as a health practitioner under the Health Professions Act, 1974 (Act No. 56 of 1974), confers certain rights and privileges. Corresponding to these rights and privileges are the ethical duties a health practitioner owes to individuals and society.
- 2.2 This booklet contains *general ethical guidelines* for health researchers. General ethical guidelines embody the ideals to which members of professions should aspire and subscribe. A failure to do so may result in disciplinary action by the HPCSA and legal consequences.
- 2.3 The ethical guidelines contained herein are drawn from a variety of sources, including the South African Constitution, the Department of Health's Ethics in Health Research: Principles, Structures and Processes, the South African Medical Research Council's Guidelines for Ethics in Medical Research and the Declaration of Helsinki.

Definitions

- 2.4 The following definitions apply:
 - 2.4.1 'Health researcher' refers to all scientific investigators engaged in health research.
 - 2.4.2 'Research participant' refers to a person who subjects himself or herself to a process of scientific or health research.
 - 2.4.3 'Health research,' as defined in the National Health Act (Act No. 61 of 2003), includes any research that contributes to the knowledge of:
 - i) The biological, clinical psychological or social processes in human beings;
 - ii) Improved methods for the provision of health services;
 - iii) Human pathology;
 - iv) The causes of diseases;
 - v) The effects of the environment on the human body;
 - vi) The development or new application of pharmaceuticals, medicines and related substances; and
 - vii) The development of new applications of health technology.
 - 2.4.4 'Research ethics committee' refers to a Committee established in terms of section 69(1) of the National Health Act;

2.4.5 'Clinical trial' refers to a systematic study involving human participants that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment.

2.4.6 According to the UNAIDS definition, 'Vulnerable communities' refers to those communities that have some or all of the following characteristics

- i) Limited economic development
- ii) Inadequate protection of human rights and discrimination on the basis of health status
- iii) Inadequate community/cultural experience with the understanding of scientific research
- iv) Limited availability of health care and treatment options
- v) Limited ability of individuals in the community to provide informed consent
- vi) Being a junior or subordinate member of a hierarchical group
- vii) Limited literacy levels

3. ETHICAL GUIDELINES IN HEALTH RESEARCH

- 3.1 Researchers conducting health research involving human participants need to consider the possible adverse impacts of their research on vulnerable groups and thus have a duty to observe the highest possible standards to protect the rights of research participants.
- 3.2 Responsible health research not only makes a *scientific* contribution for the good of humans or animals, but is also conducted in an *ethical* manner.
- 3.3 For research to be ethical, guidelines need to be followed. Such guidelines flow from underlying ethical values, standards, and principles. Effective guidelines contribute to achieving health research that is scientifically, ethically and legally sound.
- 3.4 Health research ethics committees use a protocol review procedure to consider all ethical questions regarding human and animal health research proposals and protocols. In terms of the National Health Act (Act No. 61 of 2003), all health research proposals and protocols require approval by an accredited health research ethics committee before the research may commence.

4. BASIC ETHICAL PRINCIPLES IN HEALTH RESEARCH

4.1 Some core ethical values and standards have the status of *basic ethical principles*.

4.1.1. *The principle of best interest or well-being*

The principle of non-maleficence: risks and harms of research to participants must be minimised.

The principle of beneficence: The benefits of health research must outweigh the risks to the research participants.

4.1.2. *The principle of respect for persons:*

The principle of autonomy: participants that are capable of deliberation about personal choices should be treated with respect for their capacity of self determination and be afforded the opportunity to make informed decisions with regard to their participation in research. Therefore there must be special protections for those with diminished or impaired autonomy i.e. dependant and or vulnerable participants need to be afforded safeguards against harm or abuse.

The principle of confidentiality: A participant's right to both privacy and confidentiality must be protected. The researcher must ensure that where personal information about research participants or a community is collected, stored, used or destroyed, this is done in ways that respect the privacy or confidentiality of participants or the community and any agreements made with the participants or the community

4.1.3. *The principle of justice*

Justice imposes an ethical obligation to treat each person in accordance with what is right and proper. In research this is primarily distributive justice whereby there should be equitable distribution of both burdens and benefits of research participation. It is an ethical imperative that the study should leave the participant and or community better off or no worse off. Researchers have an obligation to justify their choice of research questions and to ensure that such questions are neither gratuitous nor result in the exploitation of study participants. The selection, recruitment, exclusion and inclusion of research participants must be just and fair, based on sound scientific and ethical principles. No persons may be inappropriately or unjustly excluded on the basis of race, age, sex, sexual orientation, disability, education, religious beliefs, pregnancy, marital status, ethnic or social origin, conscience, belief or language.

Where research involves participants from vulnerable communities, added protections will be necessary to safeguard their vulnerabilities. There needs to be justification for doing research in vulnerable communities. Moreover, the research should be responsive to their particular vulnerabilities. Enhanced or added consent procedures would be necessary where appropriate. Vulnerable communities should not be targeted for research just because of administrative and logistical ease of availability.

5. THE SOCIAL VALUE OF RESEARCH

5.1 Research in South Africa should be responsive to the health needs of our communities and in line with our national health research priorities as outlined in section 70 of the National Health Act. The following factors should be taken into consideration:

- 5.1.1 The burden of disease;
- 5.1.2 The cost-effectiveness of interventions aimed at reducing the burden of disease;
- 5.1.3 The availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities;
- 5.1.4 The health needs of vulnerable groups such as women, older persons, children and people with disabilities; and
- 5.1.5 The health needs of communities.

6. DUTIES TO RESEARCH PARTICIPANTS

6.1 ACTING IN THE BEST INTERESTS OF RESEARCH PARTICIPANTS

In order to always act in the best interests of research participants, health researchers should always:

- 6.1.1 Place the life, well being, health, privacy and dignity of their research participants before all other interests.
- 6.1.2 Honour the trust that research participants place in them.

- 6.1.3 Recognise that they are in a position of power over research participants and should avoid abusing their position.
- 6.1.4 Abstain from engaging in research projects involving human research participants unless they are in no doubt that the risks involved have been adequately assessed and can be satisfactorily managed throughout the duration of the project.
- 6.1.5 Stop the involvement of research participants if continuation of the research may be harmful to them or where it becomes obvious that the risks are outweighing the benefits.
- 6.1.6 Be accessible to research participants in the course of their investigations.
- 6.1.7 Ensure that their personal beliefs do not influence their choice of research participants. Such beliefs may prejudice choices regarding the lifestyle, culture, beliefs, race, colour, gender, sexual orientation, age, social status, or perceived economic worth of research participants, and will be unethical.
- 6.1.8 Respond to criticism and complaints promptly and constructively.
- 6.1.9 Report violations and seek redress, if possible, in circumstances where they believe that violations of the rights of research participants are taking place.
- 6.1.10 Ensure that research participants are compensated for all reasonable expenses or loss of income incurred as a result of their participation in research and such compensation should be specified in the relevant research protocol or proposal.
- 6.1.11 Ensure that all research participants are compensated for trial related injuries and that there is adequate insurance cover for research participants. .
- 6.1.12 Ensure that no undue inducements are offered to participants to encourage them to participate in the research by exploiting their unfavourable socio – economic status.
- 6.1.13 Ensure at the end of a drug trial that on-going treatment where needed/necessary is available to research participants.

6.2	RESPECT FOR RESEARCH PARTICIPANTS
------------	--

In order to demonstrate respect for their research participants, health researchers should always:

- 6.2.1 Respect the privacy and dignity of research participants.
- 6.2.2 Treat research participants politely and with consideration.
- 6.2.3 Listen to the research participants and respect their opinions.
- 6.2.4 Respect the right of research participants to safeguard their integrity.
- 6.2.5 Avoid improper relations with research participants, their friends or family members.
- 6.2.6 Remember that contemporary societal reactions to particular diseases may place research participants at risk and this must be taken into account when selecting research participants.

- 6.2.7 Guard against human-rights violations and avoid participating in any actions that violate the rights of others.

6.3	INFORMED CONSENT
-----	------------------

Health researchers should always:

- 6.3.1 Give research participants sufficient information about the nature and effect of the research - in particular the effect of the research on the participants including its consequences, risks and benefits - to enable them to make an informed choice about their participation.
- 6.3.2 Give research participants the information they ask for and need about their research participation.
- 6.3.4 Remember that responsibility for the well-being of research participants always rests with the health researcher - not the research participants - even though the latter have given consent.
- 6.3.5 Give information to research participants in a language that the participant understands and in a manner that takes into account the participant's level of literacy, understanding, values and personal belief systems. Participation at all times should be voluntary and not coerced.
- 6.3.6 Use caution when obtaining informed consent where the research participant is in a dependent relationship with the health researcher or is in a situation where he or she may consent under duress. In such cases, informed consent should be obtained by a well-informed health care practitioner who is not engaged in the research and who is completely independent of this relationship.
- 6.3.7 Refrain from purposefully withholding from research participants any information, investigation or procedure that health care practitioners know is in the best interests of the participants.
- 6.3.8 Obtain the consent of legally authorised representatives in cases of research participants who cannot consent for themselves, e.g. children, mentally challenged, elderly and the unconscious. These groups should not be included in research unless the research is necessary to promote the health of the population represented and unless this research cannot instead be performed on legally competent persons.
- 6.3.9 Remember that the principle of informed consent should be viewed as an on-going process in that research participants are entitled to change their minds. Moreover, the consent process should be reinforced during the trial.
- 6.3.10 Inform research participants of their right to abstain from participating in the study, or to withdraw from participating in the study - by revoking their consent - at any time, without suffering prejudice or reprisal.
- 6.3.11 Allow competent research participant's unimpeded access throughout the research period to information concerning the research.
- 6.3.12 Inform participants of the limits to the confidentiality of the information about them gathered during the research - e.g. bodies such as the National Health Research

Ethics Council, the HPCSA, and the Medicines Control Council may review or inspect data.

- 6.3.13 Adhere to the principle of informed consent by keeping proper documentation. After ensuring that the research participant understands the information, the health researcher should obtain the participant's freely given informed consent in writing. If the consent cannot be obtained in writing, the non-written consent must be fully documented and witnessed. Both verbal and written informed consent must be obtained unless there are good reasons for not doing so. Where the research participant is not literate verbal consent should be obtained in the presence of an independent literate witness who should verify this in writing. Where the independent witness is not literate, the consent process should be audio-visually recorded.

6.4 RESEARCH PARTICIPANT CONFIDENTIALITY

Health researchers should always:

- 6.4.1 Recognise the right of research participants to expect that health researchers will not pass on any personal and confidential information that the latter learn in the course of their professional duties, unless the research participants agree.
- 6.4.2 Not breach confidentiality without sound reason and without the knowledge and consent of the research participants.
- 6.4.3 Protect the confidentiality of research data or other disclosures made by research participants.

6.5 IMPARTIALITY AND JUSTICE

Health researchers must always:

- 6.5.1 Be aware of the rights and laws concerning unfair discrimination in the management of research participants or their families on the basis of race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability such as contained in health-rights legislation.
- 6.5.2 Not discriminate in the selection and recruitment of participants by including or excluding them on the grounds of race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability, except where the exclusion or inclusion of particular groups is critical to the research purpose and scientific design.
- 6.5.3 Design research projects so that the selection, recruitment, exclusion or inclusion of research participants is fair and equitable.
- 6.5.4 Balance the burdens and benefits of research within different population groups.
- 6.5.5 Avoid imposing an unfair burden of research participation on particular groups and communities, who are likely to be subject to over-researching.

6.6	HEALTH RESEARCH AND MEDICAL HEALTH CARE
-----	---

Health care should not be assumed to refer to drug treatments only. It extends to considerations of all other aspects of health care under the control of the investigator.

In all instances, health researchers should:

- 6.6.1 Combine health research with medical care only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value.
- 6.6.2 Test the benefits and burdens, risks and effectiveness of new methods against those of the best current prophylactic, diagnostic and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic and therapeutic method exists.
- 6.6.3 At the conclusion of their study, ensure that research participants have access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.
- 6.6.4 Fully inform research participants about which aspects of medical care, if any, are related to health research, and clearly distinguish between therapeutic interventions and health research processes.
- 6.6.5 Ensure that research participants understand that the health researcher's role as a researcher differs from their role as health care practitioners.
- 6.6.6 Promote access to health care. Should health researchers be unable to provide the required research related health care for research participants they should refer the research participants to another health care practitioner or healthcare facility. The costs of this care should be the responsibility of the researcher and sponsor.
- 6.6.7 Ensure that in multi-centre and multi-national studies, equal standards of care are applied across countries to all research participants

6.7	POTENTIAL CONFLICTS OF INTEREST
-----	---------------------------------

All health researchers should:

- 6.7.1 Declare to all research participants any conflicts of interest they may have in institutions, equipment, research sponsors etc. This includes the need to declare whether the research is being conducted for academic purposes.
- 6.7.2 Disclose any potential conflicts of interest to their research ethics committee before the research commences.
- 6.7.3 Design their research to exclude any potential conflicts of interest with sponsors or collaborators.

7. DUTIES TO RESEARCH COLLEAGUES AND OTHER PROFESSIONALS

Health researchers should always:

- 7.1 Work with and respect other health care practitioners in pursuit of the best health care possible for all research participants.
- 7.2 Not discriminate against colleagues because of their race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability.
- 7.3 Not allow research participants to doubt the knowledge or skills of colleagues by making unnecessary or unsubstantiated comments about them.
- 7.4 Refrain from unjustifiably hindering other colleagues who wish to conduct research in similar fields.

8. DUTIES TO HEALTH RESEARCHERS THEMSELVES

8.1 KNOWLEDGE AND SKILLS

- 8.1.1 Health researchers who are suitably qualified should conduct health research studies. In all cases including multi-national collaborative research the local primary investigator must be a South African based researcher (i.e. a person who is permanently based in South Africa). The Principal Investigator must be registered with the HPCSA and must be responsible for the ethical management of study.
- 8.1.2 All health researchers should always:
 - 8.1.2.1 Maintain and improve the standard of their performance by keeping their professional knowledge and skills up to date throughout their working life. In particular, they should regularly take part in educational activities that enhance their scientific and research ethics knowledge.
 - 8.1.2.2 Acknowledge the limits of their professional knowledge and competence.
 - 8.1.2.3 Observe and keep up to date with the ethical and regulatory frameworks that affect health research.

8.2 EQUIPMENT, HYGIENE, AND RECORD KEEPING

Health researchers should always:

- 8.2.1 Keep their research equipment in good working order.
- 8.2.2 Maintain proper hygiene in their working environment.
- 8.2.3 Keep accurate and up-to-date records about research participants.

9. DUTIES TO SOCIETY

9.1. RESPECT FOR LIFE

- 9.1.1 Health researchers should treat all living objects - humans, animals and plants - with the necessary and appropriate respect.
- 9.1.2 Animals should not be used in research requiring them to be harmed or sacrificed where alternative methods such as computer-generated models can be used to achieve the same results.

9.2 REPORTING SCIENTIFIC MISCONDUCT

Health researchers should report evidence of fraud and other crimes or scientific misconduct in research to the HPCSA.

- 9.2.1 Scientific misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- 9.2.2 Fabrication is making up data or results and recording or reporting them
- 9.2.3 Falsification is manipulating research material, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- 9.2.4 Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit
- 9.2.5 Scientific misconduct does not include honest error or honest difference of opinion
Definition available at http://www.ostp.gov/html/001207_3.htm
- 9.2.6 Scientific misconduct also includes but is not limited to:
 - Failure of obtaining informed consent
 - Inappropriate disclosure of research participant data
 - Deviation from approved protocol
 - Falsification of credentials
 - Deception in the research proposal

9.3 ACCESS TO SCARCE RESOURCES

Health researchers should always:

- 9.3.1 Deal responsibly with scarce health care resources, and should refrain from research that duplicates other research unnecessarily.
- 9.3.2 Refrain from any form of resource wastage in carrying out their research.
- 9.3.3 Refrain from participating in improper financial arrangements that escalate costs or disadvantage research participants, patients or institutions unfairly.
- 9.3.4 Design and conduct research to include or provide the use of appropriate facilities, in order to manage any rising contingencies.
- 9.3.5 Avoid research that impacts adversely on public health facilities.

9.4	LEGAL REQUIREMENTS
------------	---------------------------

Health researchers should always:

- 9.4.1 Conform to relevant legal requirements and ensure that their research is lawful.
- 9.4.2 Adhere to ethical guidelines. Where the ethical guidelines prescribe a higher standard than the law, health researchers should conform to the higher standard.
- 9.4.3 Ensure that at all times research is conducted or supervised by experienced, qualified, competent and ethical health researchers who are approved by all the legally required bodies.

10.	DUTIES TO THE HEALTH CARE PROFESSION
------------	---

10.1	REVIEW PROCESSES
-------------	-------------------------

The following research guidelines are applicable to all health care practitioners registered with the HPCSA irrespective of where they conduct their research.

Health researchers should:

- 10.1.1 Receive approval for their research projects from all the relevant committees before beginning the project. This includes bodies like the MCC, Provincial and hospital authorities and the National Department of Health where applicable.
- 10.1.2 Notify all relevant reviewing bodies if the risks to research participants are found to be disproportionate to the benefits during the course of the trial.
- 10.1.3 Inform relevant reviewing bodies and institutions of any changes to their research protocol.
- 10.1.4 Ensure that the health research institutions with which they work are accredited by the National Health Research Ethics Council (NHREC) and have established or provided access to an accredited health research ethics committee which is registered with the NHREC.
- 10.1.5 Report inadequate or inappropriate reviews of research protocols to the HPCSA.
- 10.1.6 Prematurely terminate a study where:
 - the research question has been answered;
 - the research proves harmful to participants

11. DUTIES TO ANIMALS

Health researchers should:

- 11.1 Accept responsibility for the care of animals used in health research and respect their welfare.
- 11.2 Demonstrate that their research is justifiable and scientifically based on literature reviews, prior observations, approved studies and, when applicable, laboratory and animal studies.
- 11.3 Follow the ethical and regulatory guidelines established at institutional level regarding the use of animals by professional associations, and by governmental authorities.
- 11.4 Use, when appropriate, inanimate materials and processes instead of animals.
- 11.5 When the use of an animal species is scientifically necessary, use lower animal species that may be less susceptible to pain and suffering - without compromising the integrity of the research.
- 11.6 When designing the research protocol, use the minimum number of animals necessary to yield valid answers to the research hypothesis.
- 11.7 Take active measures to use procedures that minimise both the incidence and severity of the pain and suffering experienced by animals.

12. DUTIES TO THE ENVIRONMENT

Health researchers should:

- 12.1.1 Ensure that the research does not impact on the environment in a manner that is harmful to the health and well-being of the population, nature and the environment. In all instances health researchers must ensure that the environment is protected for the benefit of present and future generations as is required by the South African Constitution.
- 12.1.2 Recognise that natural resources are limited and guard against their exploitation.
- 12.1.3 Health researchers should protect the environment and the public by assuring that health care waste is disposed off legally and in an environmentally friendly manner

13. DATA AND SPECIMEN STORAGE AND TRANSFER

- 13.1 Data and specimens obtained as a result of research activity should be securely stored.
- 13.2 Data, including tape recordings should be stored for a minimum of 2 years after publication or 6 years in the absence of publication.
- 13.3 There must be justifiable reasons and benefits for the country which should be provided to Research Ethics Committees for data and specimens to leave the country. This should

only be done after a Material Transfer Agreement has been signed and submitted to the local Research Ethics Committee.

13.4 The Protection of Personal Information Act 4 of 2013 (Act No. 4 of 2013) protects personal information by restricting how it can be used and collected by individuals and organisations by providing that:

- 13.4.1 The party processing the personal information must comply with the Act (s 8);
- 13.4.2 The processing of personal information must be done so that it does not infringe the privacy of the data subject (the individual whose data is collected) (ss 9-12);
- 13.4.3 The personal information must only be collected for a specific purpose and the data subject must be told about this (s 13);
- 13.4.4 The records may not be held longer than is necessary to achieve the purpose for which they were collected (s 14);
- 13.4.5 Further processing of the information must be in line with the purpose of collecting it (s 15);
- 13.4.6 The party holding the personal information must ensure that it is complete, accurate, not misleading and updated when required (s 16);
- 13.4.7 The party holding the data must ensure that the data subject knows that the personal information has been collected and the purpose of the collection (s 18);
(h) the party holding the personal information must secure the personal data under their control (s 19);
- 13.4.8 The party holding the information must inform the data subject if there is a breach of security (ss 21 and 22);
- 13.4.9 A data subject may enquire whether a person or organisation holds their personal information and what the information is (s 23);
- 13.4.10 The data subject may request the correction or deletion of personal information that is inaccurate, irrelevant, excessive, out of date, incomplete, misleading or obtained unlawfully (s 24).



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

**GENERAL ETHICAL GUIDELINES FOR
HEALTH RESEARCHERS**

BOOKLET 14

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax: (012) 328 4863

E-mail: hpcsa@hpcsa.co.za

Website: <http://www.hpcsa.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care professional requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practice as a health care professional is a moral enterprise. In this spirit the Health Professions Council of South Africa presents the following ethical guidelines.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1. PREAMBLE	1
2. INTRODUCTION	1
3. ETHICAL GUIDELINES IN HEALTH RESEARCH.....	2
4. BASIC ETHICAL PRINCIPLES IN HEALTH RESEARCH.....	2
5. THE SOCIAL VALUE OF RESEARCH	3
6. DUTIES TO RESEARCH PARTICIPANTS	3
7. DUTIES TO RESEARCH COLLEAGUES AND OTHER PROFESSIONALS.....	8
8. DUTIES TO HEALTH RESEARCHERS THEMSELVES.....	8
9. DUTIES TO SOCIETY	8
10. DUTIES TO THE HEALTH CARE PROFESSION	10
11. DUTIES TO ANIMALS	10
12. DUTIES TO THE ENVIRONMENT.....	11
13. DATA AND SPECIMEN STORAGE.....	11

GENERAL ETHICAL GUIDELINES FOR HEALTH RESEARCHERS

1. PREAMBLE

Biomedical research has made spectacular strides during the past century. That medical research has increased the well being of humans in much of the world is without doubt but the power to save human lives and ameliorate disease has also raised concerns about how this is achieved and how its fruits will be distributed. South Africa with its scientific expertise, advanced infrastructure, developing country burden of disease and large number of vulnerable populations provides fertile ground for research. Moreover the country is still recovering from its many years under apartheid. Hence the misuse of power in research cannot be ignored. The following guidelines should serve as a reference to research institutions, organisation and researchers registered with the HPCSA

2. INTRODUCTION

- 2.1 Being registered as a health practitioner under the Health Professions Act, 1974 (Act No. 56 of 1974), confers certain rights and privileges. Corresponding to these rights and privileges are the ethical duties a health practitioner owes to individuals and society.
- 2.2 This booklet contains *general ethical guidelines* for health researchers. General ethical guidelines embody the ideals to which members of professions should aspire and subscribe. A failure to do so may result in disciplinary action by the HPCSA and legal consequences.
- 2.3 The ethical guidelines contained herein are drawn from a variety of sources, including the South African Constitution, the Department of Health's Ethics in Health Research: Principles, Structures and Processes, the South African Medical Research Council's Guidelines for Ethics in Medical Research and the Declaration of Helsinki.

Definitions

- 2.4 The following definitions apply:
- 2.4.1 'Health researcher' refers to all scientific investigators engaged in health research.
- 2.4.2 'Research participant' refers to a person who subjects himself or herself to a process of scientific or health research.
- 2.4.3 'Health research,' as defined in the National Health Act (Act No. 61 of 2003), includes any research that contributes to the knowledge of:
- i The biological, clinical psychological or social processes in human beings;
 - ii Improved methods for the provision of health services;
 - iii Human pathology;
 - iv The causes of diseases;
 - v The effects of the environment on the human body;
 - vi The development or new application of pharmaceuticals, medicines and related substances; and
 - vii The development of new applications of health technology.
- 2.4.4 'Research ethics committee' refers to a Committee established in terms of section 69(1) of the National Health Act;

- 2.4.5 'Clinical trial' refers to a systematic study involving human participants that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment.
- 2.4.6 According to the UNAIDS definition, 'Vulnerable communities' refers to those communities that have some or all of the following characteristics
- i. Limited economic development
 - ii. Inadequate protection of human rights and discrimination on the basis of health status
 - iii. Inadequate community/cultural experience with the understanding of scientific research
 - iv. Limited availability of health care and treatment options
 - v. Limited ability of individuals in the community to provide informed consent
 - vi. Being a junior or subordinate member of a hierarchical group
 - vii. Limited literacy levels

3. ETHICAL GUIDELINES IN HEALTH RESEARCH

- 3.1 Researchers conducting health research involving human participants need to consider the possible adverse impacts of their research on vulnerable groups and thus have a duty to observe the highest possible standards to protect the rights of research participants.
- 3.2 Responsible health research not only makes a *scientific* contribution for the good of humans or animals, but is also conducted in an *ethical* manner.
- 3.3 For research to be ethical, guidelines need to be followed. Such guidelines flow from underlying ethical values, standards, and principles. Effective guidelines contribute to achieving health research that is scientifically, ethically and legally sound.
- 3.4 Health research ethics committees use a protocol review procedure to consider all ethical questions regarding human and animal health research proposals and protocols. In terms of the National Health Act (Act No. 61 of 2003), all health research proposals and protocols require approval by an accredited health research ethics committee before the research may commence.

4. BASIC ETHICAL PRINCIPLES IN HEALTH RESEARCH

- 4.1 Some core ethical values and standards have the status of *basic ethical principles*.

4.1.1. *The principle of best interest or well-being*

The principle of non-maleficence: risks and harms of research to participants must be minimised.

The principle of beneficence: The benefits of health research must outweigh the risks to the research participants.

4.1.2. *The principle of respect for persons:*

The principle of autonomy: participants that are capable of deliberation about personal choices should be treated with respect for their capacity of self determination and be afforded the opportunity to make informed decisions with regard to their participation in research. Therefore there must be special protections for those with diminished or impaired autonomy i.e. dependant and or vulnerable participants need to be afforded safeguards against harm or abuse.

The principle of confidentiality: A participant's right to both privacy and confidentiality must be protected. The researcher must ensure that where personal information about research participants or a community is collected, stored, used or destroyed, this is done in ways that respect the privacy or confidentiality of participants or the community and any agreements made with the participants or the community

4.1.3. *The principle of justice*

Justice imposes an ethical obligation to treat each person in accordance with what is right and proper. In research this is primarily distributive justice whereby there should be equitable distribution of both burdens and benefits of research participation. It is an ethical imperative that the study should leave the participant and or community better off or no worse off. Researchers have an obligation to justify their choice of research questions and to ensure that such questions are neither gratuitous nor result in the exploitation of study participants. The selection, recruitment, exclusion and inclusion of research participants must be just and fair, based on sound scientific and ethical principles. No persons may be inappropriately or unjustly excluded on the basis of race, age, sex, sexual orientation, disability, education, religious beliefs, pregnancy, marital status, ethnic or social origin, conscience, belief or language.

Where research involves participants from vulnerable communities, added protections will be necessary to safeguard their vulnerabilities. There needs to be justification for doing research in vulnerable communities. Moreover, the research should be responsive to their particular vulnerabilities. Enhanced or added consent procedures would be necessary where appropriate. Vulnerable communities should not be targeted for research just because of administrative and logistical ease of availability.

5. THE SOCIAL VALUE OF RESEARCH

5.1 Research in South Africa should be responsive to the health needs of our communities and in line with our national health research priorities as outlined in section 70 of the National Health Act. The following factors should be taken into consideration:

- 5.1.1 The burden of disease;
- 5.1.2 The cost-effectiveness of interventions aimed at reducing the burden of disease;
- 5.1.3 The availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities;
- 5.1.4 The health needs of vulnerable groups such as women, older persons, children and people with disabilities; and
- 5.1.5 The health needs of communities.

6. DUTIES TO RESEARCH PARTICIPANTS

6.1 ACTING IN THE BEST INTERESTS OF RESEARCH PARTICIPANTS

In order to always act in the best interests of research participants, health researchers should always:

- 6.1.1 Place the life, well being, health, privacy and dignity of their research participants before all other interests.
- 6.1.2 Honour the trust that research participants place in them.

- 6.1.3 Recognise that they are in a position of power over research participants and should avoid abusing their position.
- 6.1.4 Abstain from engaging in research projects involving human research participants unless they are in no doubt that the risks involved have been adequately assessed and can be satisfactorily managed throughout the duration of the project.
- 6.1.5 Stop the involvement of research participants if continuation of the research may be harmful to them or where it becomes obvious that the risks are outweighing the benefits.
- 6.1.6 Be accessible to research participants in the course of their investigations.
- 6.1.7 Ensure that their personal beliefs do not influence their choice of research participants. Such beliefs may prejudice choices regarding the lifestyle, culture, beliefs, race, colour, gender, sexual orientation, age, social status, or perceived economic worth of research participants, and will be unethical.
- 6.1.8 Respond to criticism and complaints promptly and constructively.
- 6.1.9 Report violations and seek redress, if possible, in circumstances where they believe that violations of the rights of research participants are taking place.
- 6.1.10 Ensure that research participants are compensated for all reasonable expenses or loss of income incurred as a result of their participation in research and such compensation should be specified in the relevant research protocol or proposal.
- 6.1.11 Ensure that all research participants are compensated for trial related injuries and that there is adequate insurance cover for research participants. .
- 6.1.12 Ensure that no undue inducements are offered to participants to encourage them to participate in the research by exploiting their unfavourable socio – economic status.
- 6.1.13 Ensure at the end of a drug trial that on-going treatment where needed/necessary is available to research participants.

6.2	RESPECT FOR RESEARCH PARTICIPANTS
-----	-----------------------------------

In order to demonstrate respect for their research participants, health researchers should always:

- 6.2.1 Respect the privacy and dignity of research participants.
- 6.2.2 Treat research participants politely and with consideration.
- 6.2.3 Listen to the research participants and respect their opinions.
- 6.2.4 Respect the right of research participants to safeguard their integrity.
- 6.2.5 Avoid improper relations with research participants, their friends or family members.
- 6.2.6 Remember that contemporary societal reactions to particular diseases may place research participants at risk and this must be taken into account when selecting research participants.

- 6.2.7 Guard against human-rights violations and avoid participating in any actions that violate the rights of others.

6.3	INFORMED CONSENT
-----	------------------

Health researchers should always:

- 6.3.1 Give research participants sufficient information about the nature and effect of the research - in particular the effect of the research on the participants including its consequences, risks and benefits - to enable them to make an informed choice about their participation.
- 6.3.2 Give research participants the information they ask for and need about their research participation.
- 6.3.4 Remember that responsibility for the well-being of research participants always rests with the health researcher - not the research participants - even though the latter have given consent.
- 6.3.5 Give information to research participants in a language that the participant understands and in a manner that takes into account the participant's level of literacy, understanding, values and personal belief systems. Participation at all times should be voluntary and not coerced.
- 6.3.6 Use caution when obtaining informed consent where the research participant is in a dependent relationship with the health researcher or is in a situation where he or she may consent under duress. In such cases, informed consent should be obtained by a well-informed health care practitioner who is not engaged in the research and who is completely independent of this relationship.
- 6.3.7 Refrain from purposefully withholding from research participants any information, investigation or procedure that health care practitioners know is in the best interests of the participants.
- 6.3.8 Obtain the consent of legally authorised representatives in cases of research participants who cannot consent for themselves, e.g. children, mentally challenged, elderly and the unconscious. These groups should not be included in research unless the research is necessary to promote the health of the population represented and unless this research cannot instead be performed on legally competent persons.
- 6.3.9 Remember that the principle of informed consent should be viewed as an on-going process in that research participants are entitled to change their minds. Moreover, the consent process should be reinforced during the trial.
- 6.3.10 Inform research participants of their right to abstain from participating in the study, or to withdraw from participating in the study - by revoking their consent - at any time, without suffering prejudice or reprisal.
- 6.3.11 Allow competent research participants unimpeded access throughout the research period to information concerning the research.
- 6.3.12 Inform participants of the limits to the confidentiality of the information about them gathered during the research - e.g. bodies such as the National Health Research

Ethics Council, the HPCSA, and the Medicines Control Council may review or inspect data.

- 6.3.13 Adhere to the principle of informed consent by keeping proper documentation. After ensuring that the research participant understands the information, the health researcher should obtain the participant's freely given informed consent in writing. If the consent cannot be obtained in writing, the non-written consent must be fully documented and witnessed. Both verbal and written informed consent must be obtained unless there are good reasons for not doing so. Where the research participant is not literate verbal consent should be obtained in the presence of an independent literate witness who should verify this in writing. Where the independent witness is not literate, the consent process should be audio-visually recorded.

6.4 RESEARCH PARTICIPANT CONFIDENTIALITY

Health researchers should always:

- 6.4.1 Recognise the right of research participants to expect that health researchers will not pass on any personal and confidential information that the latter learn in the course of their professional duties, unless the research participants agree.
- 6.4.2 Not breach confidentiality without sound reason and without the knowledge and consent of the research participants.
- 6.4.3 Protect the confidentiality of research data or other disclosures made by research participants.

6.5 IMPARTIALITY AND JUSTICE

Health researchers must always:

- 6.5.1 Be aware of the rights and laws concerning unfair discrimination in the management of research participants or their families on the basis of race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability such as contained in health-rights legislation.
- 6.5.2 Not discriminate in the selection and recruitment of participants by including or excluding them on the grounds of race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability, except where the exclusion or inclusion of particular groups is critical to the research purpose and scientific design.
- 6.5.3 Design research projects so that the selection, recruitment, exclusion or inclusion of research participants is fair and equitable.
- 6.5.4 Balance the burdens and benefits of research within different population groups.
- 6.5.5 Avoid imposing an unfair burden of research participation on particular groups and communities, who are likely to be subject to over-researching.

6.6 HEALTH RESEARCH AND MEDICAL HEALTH CARE

Health care should not be assumed to refer to drug treatments only. It extends to considerations of all other aspects of health care under the control of the investigator.

In all instances, health researchers should:

- 6.6.1 Combine health research with medical care only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value.
- 6.6.2 Test the benefits and burdens, risks and effectiveness of new methods against those of the best current prophylactic, diagnostic and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic and therapeutic method exists.
- 6.6.3 At the conclusion of their study, ensure that research participants have access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.
- 6.6.4 Fully inform research participants about which aspects of medical care, if any, are related to health research, and clearly distinguish between therapeutic interventions and health research processes.
- 6.6.5 Ensure that research participants understand that the health researcher's role as a researcher differs from their role as health care practitioners.
- 6.6.6 Promote access to health care. Should health researchers be unable to provide the required research related health care for research participants they should refer the research participants to another health care practitioner or healthcare facility. The costs of this care should be the responsibility of the researcher and sponsor.
- 6.6.7 Ensure that in multi-centre and multi-national studies, equal standards of care are applied across countries to all research participants

6.7 POTENTIAL CONFLICTS OF INTEREST

All health researchers should:

- 6.7.1 Declare to all research participants any conflicts of interest they may have in institutions, equipment, research sponsors etc. This includes the need to declare whether the research is being conducted for academic purposes.
- 6.7.2 Disclose any potential conflicts of interest to their research ethics committee before the research commences.
- 6.7.3 Design their research to exclude any potential conflicts of interest with sponsors or collaborators.

7. DUTIES TO RESEARCH COLLEAGUES AND OTHER PROFESSIONALS

Health researchers should always:

- 7.1 Work with and respect other health care practitioners in pursuit of the best health care possible for all research participants.
- 7.2 Not discriminate against colleagues because of their race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability.
- 7.3 Not allow research participants to doubt the knowledge or skills of colleagues by making unnecessary or unsubstantiated comments about them.
- 7.4 Refrain from unjustifiably hindering other colleagues who wish to conduct research in similar fields.

8. DUTIES TO HEALTH RESEARCHERS THEMSELVES

8.1 KNOWLEDGE AND SKILLS

- 8.1.1 Health researchers who are suitably qualified should conduct health research studies. In all cases including multi-national collaborative research the local primary investigator must be a South African based researcher (i.e. a person who is permanently based in South Africa). The Principal Investigator must be registered with the HPCSA and must be responsible for the ethical management of study.
- 8.1.2 All health researchers should always:
 - 8.1.2.1 Maintain and improve the standard of their performance by keeping their professional knowledge and skills up to date throughout their working life. In particular, they should regularly take part in educational activities that enhance their scientific and research ethics knowledge.
 - 8.1.2.2 Acknowledge the limits of their professional knowledge and competence.
 - 8.1.2.3 Observe and keep up to date with the ethical and regulatory frameworks that affect health research.

8.2 EQUIPMENT, HYGIENE, AND RECORD KEEPING

Health researchers should always:

- 8.2.1 Keep their research equipment in good working order.
- 8.2.2 Maintain proper hygiene in their working environment.
- 8.2.3 Keep accurate and up-to-date records about research participants.

9. DUTIES TO SOCIETY

9.1. RESPECT FOR LIFE

- 9.1.1 Health researchers should treat all living objects - humans, animals and plants - with the necessary and appropriate respect.
- 9.1.2 Animals should not be used in research requiring them to be harmed or sacrificed where alternative methods such as computer-generated models can be used to achieve the same results.

9.2 REPORTING SCIENTIFIC MISCONDUCT

Health researchers should report evidence of fraud and other crimes or scientific misconduct in research to the HPCSA.

- 9.2.1 Scientific misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- 9.2.2 Fabrication is making up data or results and recording or reporting them
- 9.2.3 Falsification is manipulating research material, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- 9.2.4 Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit
- 9.2.5 Scientific misconduct does not include honest error or honest difference of opinion
Definition available at http://www.ostp.gov/html/001207_3.htm
- 9.2.6 Scientific misconduct also includes but is not limited to:
- Failure of obtaining informed consent
 - Inappropriate disclosure of research participant data
 - Deviation from approved protocol
 - Falsification of credentials
 - Deception in the research proposal

9.3 ACCESS TO SCARCE RESOURCES

Health researchers should always:

- 9.3.1 Deal responsibly with scarce health care resources, and should refrain from research that duplicates other research unnecessarily.
- 9.3.2 Refrain from any form of resource wastage in carrying out their research.
- 9.3.3 Refrain from participating in improper financial arrangements that escalate costs or disadvantage research participants, patients or institutions unfairly.
- 9.3.4 Design and conduct research to include or provide the use of appropriate facilities, in order to manage any rising contingencies.
- 9.3.5 Avoid research that impacts adversely on public health facilities.

9.4 LEGAL REQUIREMENTS

Health researchers should always:

- 9.4.1 Conform to relevant legal requirements and ensure that their research is lawful.
- 9.4.2 Adhere to ethical guidelines. Where the ethical guidelines prescribe a higher standard than the law, health researchers should conform to the higher standard.
- 9.4.3 Ensure that at all times research is conducted or supervised by experienced, qualified, competent and ethical health researchers who are approved by all the legally required bodies.

10. DUTIES TO THE HEALTH CARE PROFESSION

10.1 REVIEW PROCESSES

The following research guidelines are applicable to all health care practitioners registered with the HPCSA irrespective of where they conduct their research.

Health researchers should:

- 10.1.1 Receive approval for their research projects from all the relevant committees before beginning the project. This includes bodies like the MCC, Provincial and hospital authorities and the National Department of Health where applicable.
- 10.1.2 Notify all relevant reviewing bodies if the risks to research participants are found to be disproportionate to the benefits during the course of the trial.
- 10.1.3 Inform relevant reviewing bodies and institutions of any changes to their research protocol.
- 10.1.4 Ensure that the health research institutions with which they work are accredited by the National Health Research Ethics Council (NHREC) and have established or provided access to an accredited health research ethics committee which is registered with the NHREC.
- 10.1.5 Report inadequate or inappropriate reviews of research protocols to the HPCSA.
- 10.1.6 Prematurely terminate a study where:
 - the research question has been answered;
 - the research proves harmful to participants

11. DUTIES TO ANIMALS

Health researchers should:

- 11.1 Accept responsibility for the care of animals used in health research and respect their welfare.

- 11.2 Demonstrate that their research is justifiable and scientifically based on literature reviews, prior observations, approved studies and, when applicable, laboratory and animal studies.
- 11.3 Follow the ethical and regulatory guidelines established at institutional level regarding the use of animals by professional associations, and by governmental authorities.
- 11.4 Use, when appropriate, inanimate materials and processes instead of animals.
- 11.5 When the use of an animal species is scientifically necessary, use lower animal species that may be less susceptible to pain and suffering - without compromising the integrity of the research.
- 11.6 When designing the research protocol, use the minimum number of animals necessary to yield valid answers to the research hypothesis.
- 11.7 Take active measures to use procedures that minimise both the incidence and severity of the pain and suffering experienced by animals.

12. DUTIES TO THE ENVIRONMENT

Health researchers should:

- 12.1.1 Ensure that the research does not impact on the environment in a manner that is harmful to the health and well-being of the population, nature and the environment. In all instances health researchers must ensure that the environment is protected for the benefit of present and future generations as is required by the South African Constitution.
- 12.1.2 Recognise that natural resources are limited and guard against their exploitation.
- 12.1.3 Health researchers should protect the environment and the public by assuring that health care waste is disposed off legally and in an environmentally friendly manner

13. DATA AND SPECIMEN STORAGE AND TRANSFER

- 13.1 Data and specimens obtained as a result of research activity should be securely stored.
- 13.2 Data, including tape recordings should be stored for a minimum of 2 years after publication or 6 years in the absence of publication.
- 13.3 There must be justifiable reasons and benefits for the country which should be provided to Research Ethics Committees for data and specimens to leave the country. This should only be done after a Material Transfer Agreement has been signed and submitted to the local Research Ethics Committee.
- 13.4 The Protection of Personal Information Act 4 of 2013 (Act No. 4 of 2013) protects personal information by restricting how it can be used and collected by individuals and organisations by providing that:
- 13.4.1 The party processing the personal information must comply with the Act (s 8);
- 13.4.2 The processing of personal information must be done so that it does not infringe the privacy of the data subject (the individual whose data is collected) (ss 9-12);

- 13.4.3 The personal information must only be collected for a specific purpose and the data subject must be told about this (s 13);
- 13.4.4 The records may not be held longer than is necessary to achieve the purpose for which they were collected (s 14);
- 13.4.5 Further processing of the information must be in line with the purpose of collecting it (s 15);
- 13.4.6 The party holding the personal information must ensure that it is complete, accurate, not misleading and updated when required (s 16);
- 13.4.7 The party holding the data must ensure that the data subject knows that the personal information has been collected and the purpose of the collection (s 18);
(h) the party holding the personal information must secure the personal data under their control (s 19);
- 13.4.8 The party holding the information must inform the data subject if there is a breach of security (ss 21 and 22);
- 13.4.9 A data subject may enquire whether a person or organisation holds their personal information and what the information is (s 23);
- 13.4.10 The data subject may request the correction or deletion of personal information that is inaccurate, irrelevant, excessive, out of date, incomplete, misleading or obtained unlawfully (s 24).



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

**RESEARCH, DEVELOPMENT AND USE OF CHEMICAL AND
BIOLOGICAL WEAPONS**

BOOKLET 15

**PRETORIA
SEPTEMBER 2016**

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300
Fax:(012) 328 4863

E-mail: hpcsa@hpcsa.co.za

Website: <http://www.hpcsa.co.za>

THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care Healthcare Practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care Healthcare Practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practice as a health care professional is a moral enterprise. In this spirit the HPCSA presents the following ethical guidelines to guide and direct the practice of health care Healthcare Practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care Healthcare Practitioner" in these guidelines refers to persons registered with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

1 PREAMBLE1

2 GLOBAL CONCERNS1

**3 TYPES OF CBW RESEARCH AND ETHICAL OBLIGATIONS OF HEALTH CARE
HEALTHCARE HEALTHCARE PRACTITIONERS2**

**4 ADOPTION OF THE WMA DECLARATIONS ON CHEMICAL AND BIOLOGICAL
WEAPONS BY THE HPCSA.....3**

ANNEXURE 1.....4

ANNEXURE 2.....6

RESEARCH, DEVELOPMENT AND USE OF CHEMICAL AND BIOLOGICAL WEAPONS: POLICY ON INVOLVEMENT OF HEALTH CARE HEALTHCARE PRACTITIONERS

1 PREAMBLE

- 1.1 The development of chemical and biological weapons (CBWs) is a major threat to global security and to the safety and health of the world's peoples. A number of countries around the world have continued to pursue scientific programmes to develop such capabilities despite international efforts to control the proliferation of these weapons of mass destruction.
- 1.2 As confirmed by the Truth and Reconciliation Commission (TRC), the South African military authorities under the apartheid government sustained a covert programme for the development of chemical and biological weapons, and recruited health care Healthcare Practitioners and scientists to staff the programme. The evidence that emerged in the TRC's investigations into this clandestine project has pointed to the importance of developing clear guidelines for the health professions in regard to participation in such programmes. It was particularly evident that the secrecy surrounding the apartheid government's CBW programme enabled health professional scientists to conduct research outside of any ethical oversight.
- 1.3 Health care Healthcare Practitioners are committed to the preservation of life and the alleviation of human suffering. It is completely contrary to the fundamental principles of the ethics of the health professions for a health care Healthcare Healthcare Practitioner to participate in research activities directed at generating materials intended to cause harm to human health and well-being. As stated in the *Declaration of Geneva* health care Healthcare Practitioners are expected to adhere to the following principle:

‘I will maintain the utmost respect for human life from its beginning even under threat and I will not use my medical knowledge contrary to the laws of humanity;’

2 GLOBAL CONCERNS

- 2.1 Fears of the consequences of the use of chemical and biological weapons (CBWs) has been exacerbated by the perception of an upsurge in global terrorism. Regrettably this concern has resulted in increased secrecy and restrictions of civil liberties in several countries around the world. This, in turn, creates a climate in which covert work on CBWs may take place under the pretext of developing defenses. Secrecy and restrictions on civil liberties are both factors that help to fuel an environment of covert activities
- 2..2 The danger of clandestine work on CBWs and the risk they pose to human rights makes it imperative that the health professions strongly condemn the development of CBWs and the participation of health care Healthcare Practitioners in their development and use.
- 2.3 The World Medical Association (WMA) in its *Declaration on Chemical and Biological Warfare* in 1990 declared that it would be “unethical for a health care Healthcare Practitioner whose missions are the preservation of life, and the provision and promotion of health care - to participate in the research, development and use of the chemical, biological and nuclear capabilities aimed at destroying life” (see below Annexure 1) In the *WMA Declaration of Washington on Biological Weapons* in 2002, the WMA reconfirmed its position that “research specifically for the purposes of creating biological weapons is to be condemned” (see below Annexure 2).

- 2.4 Article 1 of the *Biological and Toxins Weapons Convention* precludes health care professionals and scientists from ever undertaking to develop, produce, acquire or retain: (a) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; (b) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict - the *Convention* renders all such actions illegal.

3 TYPES OF CBW RESEARCH AND ETHICAL OBLIGATIONS OF HEALTH CARE HEALTHCARE PRACTITIONERS
--

- 3.1 All research to develop CBWs designed to inflict harm on humans is unethical and health care Healthcare care Practitioners find themselves in dual loyalty situations where they are coerced or experience pressure or threats to comply from the military or other authorities, they should appeal to the HPCSA or any other appropriate professional body for support in resisting such pressures.
- 3.2 No distinction should be made between what have been called “defensive” and “offensive” CBWs. Weapons that have the capacity to inflict harm should be treated as offensive weapons, notwithstanding any claims or intentions that they will be used for non-offensive purposes. Where technologies are being developed to protect military or civilian personnel against CBWs, such research should be subject to open peer review and ethical oversight by a suitably appointed independent body, as indicated below.
- 3.3 A Healthcare Practitioner who is or becomes involved in research related to combating the effects of CBWs, shall obtain prior permission from the relevant professional board of the HPCSA to conduct such research and, for that purpose the Healthcare Healthcare Practitioner shall:
- 3.3.1 Provide full particulars of the nature and scope of the envisaged research, development and use;
 - 3.3.2 Specify whether the protocols pertaining to such research have been passed by a professionally recognised research ethics committee;
 - 3.3.3 Specify how such research, development and use shall be permissible within the provisions of the World Medical Association’s *Declaration on Chemical and Biological Weapons* (1990); and
 - 3.3.4 Specify how such research, development or use is permitted in terms of the provisions of applicable international treaties or conventions to which South Africa is a signatory.
- 3.4 It is recommended that where military secrecy restricts civilian access to the research for reasons of military security, an ethics committee be established by the military authorities which includes suitably qualified civilian participants with expertise in human rights and ethics, to provide ethical oversight over any CBW-related research, consistent with the provisions of these guidelines and the relevant WMA Declarations.
- 3.5 Notwithstanding the condemnation of direct participation in CBW research, and the restrictions on research involving protection against CBW agents, there is a third category of research attracting ethical concerns. This relates to the misuse of bona fide biotechnology research for purposes of producing weapons from biological agents, particularly biological agents created through genetic manipulation of micro-organisms to increase virulence and pathogenicity. This type of research may be conducted by

researchers who have no connection to CBW programmes or who intend to allow their research to be used for such purposes, but who are not aware of or able to control the uses to which their research findings are put. Such research has been labeled “dual-use” research because it has peaceful intentions but may be used for non-peaceful purposes. Dual-use research requires careful evaluation for its ethical implications and demands added ethical oversight prior to approval of the research. Health care Healthcare Practitioners involved in such research must therefore ensure that no such research is conducted without ethical consideration of the possible misuse of the study findings to develop CBW agents.

- 3.6 Health care Healthcare Practitioners are required to ensure that they are familiar with the provisions of the Non-Proliferation of Weapons of Mass Destruction Act, which are consistent with these guidelines.

4	ADOPTION OF THE WMA DECLARATIONS ON CHEMICAL AND BIOLOGICAL WEAPONS BY THE HPCSA
----------	---

- 4.1 The HPCSA has adopted the WMA’s *Declaration on Chemical and Biological Weapons* (1990) and the WMA *Declaration of Washington on Biological Weapons* (2002) which have been reproduced below as Annexures 1 and 2 respectively.
- 4.2 The term “physician” as used in the Declarations refers to health care Healthcare Practitioners and, for the purposes of the HPCSA, should be understood to include all health care Healthcare Practitioners who fall under the jurisdiction of the HPCSA.
- 4.3 Health care Healthcare Practitioners who breach the above guidelines or the provisions of the WMA Declarations of 1990 or 2002 as reproduced in Annexures 1 and 2 below may face disciplinary action by the HPCSA.

ANNEXURE 1

WORLD MEDICAL ASSOCIATION DECLARATION ON CHEMICAL AND BIOLOGICAL WEAPONS (1990)

[Adopted by the 42nd World Medical Assembly, Rancho Mirage, CA, USA, October 1990]

1. The World Medical Association draws the attention of the medical profession throughout the world to the dangers presented by chemical and biological weapons. Among other, more obvious dangers, it should be noted as follows:
 - a. The use of such weapons would have a devastating effect on civilian populations in addition to military personnel, and not only in the target area, but also in distant places, perhaps beyond the national boundaries of the combatants.
 - b. The effects of exposure to chemical and biological weapons present a continuing threat to the health of human beings on a long term basis, possibly causing illness, injury, disease and defects in the population over a long period of time.
 - c. The effects of exposure to chemical and biological weapons may also result in permanent, complex and unpredictable changes in the natural environment, including animals, plant life and water supply, thus destroying the food source of human beings and resulting in extensive morbidity.
 - d. Existing health care services, technology and manpower may be helpless to relieve the suffering caused by exposure to chemical and biological weapons.
2. The World Medical Association Declaration of Geneva asks physicians to consecrate their lives to the service of humanity, to pledge that the health of the patient will be the physician's first consideration, and that the physician will not use medical knowledge contrary to the laws of humanity.
3. The World Medical Association Declaration of Helsinki states that it is the mission of the physician to safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this mission.
4. The World Medical Association Declaration of Tokyo begins with the following statement:

"It is the privilege of the medical health care Healthcare Practitioner to practice medicine in the service of humanity, to preserve and restore bodily and mental health without distinction as to persons, to comfort and ease the suffering of his or her patients. The utmost respect for human life is to be maintained even under threat, and no use made of any medical knowledge contrary to the laws of humanity".
5. Therefore, the World Medical Association considers that it would be unethical for the physician, whose mission is to provide health care, to participate in the research and development of chemical and biological weapons, and to use his or her personal and scientific knowledge in the conception and manufacture of such weapons.
6. Furthermore, the World Medical Association -

- a. Condemns the development and use of chemical and biological weapons;
- b. Asks all Governments to refrain from the development and use of chemical and biological weapons;
- c. Asks all National Medical Associations to join the World Medical Association in actively supporting this Declaration.

ANNEXURE 2

THE WMA DECLARATION OF WASHINGTON ON BIOLOGICAL WEAPONS

[Adopted by the WMA General Assembly, Washington 2002]

A. INTRODUCTION

1. The World Medical Association recognizes the growing threat that biological weapons might be used to cause devastating epidemics that could spread internationally. All countries are potentially at risk. The release of organisms causing smallpox, plague, anthrax or other diseases could prove catastrophic in terms of the resulting illnesses and deaths compounded by the panic such outbreaks would generate. At the same time, there is a growing potential for production of new microbial agents, as expertise in biotechnology grows and methods for genetic manipulation of organisms become simpler. These developments are of special concern to medical and public health professionals because it is they who best know the potential human suffering caused by epidemic disease and it is they who will bear primary responsibility for dealing with the victims of biological weapons. Thus, the World Medical Association believes that medical associations and all who are concerned with health care bear a special responsibility to lead in educating the public and policy makers about the implications of biological weapons and to mobilize universal support for condemning research, development, or use of such weapons as morally and ethically unacceptable.
2. Unlike the use of nuclear, chemical, and conventional weapons, the consequences of a biological attack are likely to be insidious. Their impact might continue with secondary and tertiary transmission of the agent, weeks or months after the initial epidemic. The consequences of a successful biological attack, especially if the infection were readily communicable, could far exceed those of a chemical or even a nuclear event. Given the ease of travel and increasing globalization, an outbreak anywhere in the world could be a threat to all nations.
3. A great many severe, acute illnesses occurring over a short span of time would almost certainly overwhelm the capacities of most health systems in both the developing and industrialized world. Health services throughout the world are struggling to meet the demands created by HIV/AIDS and antimicrobial-resistant organisms, the problems created by civil strife, refugees and crowded, unsanitary urban environments as well as the increased health needs of aging populations. Coping over a short period of time with large numbers of desperately ill persons could overwhelm entire health systems.
4. Actions can be taken to diminish the risk of biological weapons as well as the potentially harmful consequences of serious epidemics whatever their origin. International collaboration is needed to build a universal consensus that

condemns the development, production, or use of biological weapons. Programs of surveillance are needed in all countries for the early detection, identification, and response to serious epidemic disease; health education and training is needed for professionals, civic leaders, and the public alike; and collaborative programs of research are needed to improve disease diagnosis, prevention, and treatment.

5. The proliferation of technology and scientific progress in biochemistry, biotechnology, and the life sciences provides the opportunity to create novel pathogens and diseases and simplified production methods for bio-weapons. The technology is relatively inexpensive and, because production is similar to that used in biological facilities such as vaccine manufacturing, it is easy to obtain. Capacity to produce and effectively disperse biological weapons exists globally, allowing extremists (acting collectively or individually) to threaten governments and endanger peoples around the world. Non proliferation and arms control measures can diminish but cannot completely eliminate the threat of biological weapons. Thus, there is a need for the creation of and adherence to a globally accepted ethos that rejects the development and use of biological weapons.

B. STRENGTHENING PUBLIC HEALTH AND DISEASE SURVEILLANCE SYSTEMS

6. A critical component in dealing with epidemic disease is a strong public health infrastructure. Investment in public health systems will enhance capacity to detect and to contain expeditiously, rare or unusual disease outbreaks, whether deliberately induced or naturally occurring. Core public health functions (disease surveillance and supporting laboratory services) are needed as a foundation for detection, investigation, and response to all epidemic threats. A more effective global surveillance program will improve response to naturally occurring infectious diseases and will permit earlier detection and characterization of new or emerging diseases.
7. It is especially important that physicians be alert to the occurrence of cases or clusters of unusual infectious diseases, to seek help from infectious disease specialists in diagnosis, and to report cases promptly to public health authorities. Because any physician may see only one or a few cases and may not recognize that an outbreak is occurring, cooperation between primary care physicians and public health authorities is especially important.
8. Public health officials, dealing with an epidemic, will require the cooperation of emergency management agencies, law enforcement officials, healthcare facilities, and a variety of community service organizations. For these different groups to work together effectively, advance planning will be important. In addition to developing surveillance activities for early detection and reporting, public health efforts should be directed toward educating primary caregivers and public health staff about potential agents that might be used, building laboratory capacity for rapid identification of biological agents, providing medical and hospital services as well as vaccines and drugs to control the epidemic.

C. ENHANCEMENT OF MEDICAL PREPAREDNESS AND RESPONSE CAPACITY

9. The first indication that a biological weapon may have been disseminated is likely to be the appearance of patients in the offices of practicing physicians, especially those in acute care settings. Physicians thus play a critical role in early detection of an outbreak and must be prepared to recognize and deal with diseases resulting from the use of biological weapons as well as other infectious disease agents and to promptly report suspicious illnesses and diseases to public health officials.
10. In the course of an epidemic, physicians will be directly involved with mass patient care, with mass immunization and antibiotic prophylaxis, with providing information to the public, and in a variety of hospital and community efforts to control the epidemic. Thus, physicians should participate with local and national health authorities to develop and implement disaster preparedness and response plans for intentional and natural infectious disease outbreaks.

D. BIOWEAPONS RESEARCH AND MEDICAL ETHICS

11. Rapid advances in microbiology, molecular biology, and genetic engineering have created extraordinary opportunities for biomedical research and hold great promise for improving human health and the quality of life. Better and more rapid diagnostic tools, novel vaccines, and therapeutic drugs can be foreseen. At the same time, there is concern about the possible misuse of research for the development of more potent biological weapons and the spread of new infectious diseases. It may be difficult to distinguish legitimate biomedical research from research by unscrupulous scientists with the malign purpose of producing more effective biological weapons.
12. All who participate in biomedical research have a moral and ethical obligation to consider the implications of possible malicious use of their findings. Through deliberate or inadvertent means, genetic modification of microorganisms could create organisms that are more virulent, are antibiotic-resistant, or have greater stability in the environment. Genetic modification of microorganisms could alter their immunogenicity, allowing them to evade natural- and vaccine-induced immunity. Advances in genetic engineering and gene therapy may allow modification of the immune response system of the target population to increase or decrease susceptibility to a pathogen or disrupt the functioning of normal host genes.
13. Research specifically for the purposes of creating biological weapons is to be condemned. As scientists and humanitarians, physicians have a societal responsibility to decry scientific research for the development and use of biological weapons and to express abhorrence for the use of biotechnology and information technologies for potentially harmful purposes.
14. Physicians and medical organizations have important societal roles in demanding a global prohibition on biological weapons and stigmatizing their use, guarding against unethical and illicit research, and mitigating civilian harm from use of biological weapons.

E. RECOMMENDATIONS

15. That the World Medical Association and National Medical Associations worldwide take an active role in promoting an international ethos condemning the development, production, or use of toxins and biological agents that have no justification for prophylactic, protective, or other peaceful purposes.
16. That the World Medical Association, National Medical Associations and healthcare workers worldwide promote, with the World Health Organization, the United Nations, and other appropriate entities, the establishment of an international consortium of medical and public health leaders to monitor the threat of biological weapons, to identify actions likely to prevent bioweapons proliferation, and to develop a coordinated plan for monitoring the worldwide emergence of infectious diseases. This plan should address: (a) international monitoring and reporting systems so as to enhance the surveillance and control of infectious disease outbreaks throughout the world; (b) the development of an effective verification protocol under the UN Biological and Toxin Weapons Convention; (c) education of physicians and public health workers about emerging infectious diseases and potential biological weapons; (d) laboratory capacity to identify biological pathogens; (e) availability of appropriate vaccines and pharmaceuticals; and (f) financial, technical, and research needs to reduce the risk of use of biological weapons and other major infectious disease threats.
17. That the World Medical Association urge physicians to be alert to the occurrence of unexplained illnesses and deaths in the community and knowledgeable of disease surveillance and control capabilities for responding to unusual clusters of diseases, symptoms, or presentations.
18. That the World Medical Association encourage physicians, National Medical Associations and other medical societies to participate with local, national, and international health authorities in developing and implementing disaster preparedness and response protocols for acts of bioterrorism and natural infectious disease outbreaks. These protocols should be used as the basis for physician and public education.
19. That the World Medical Association urge all who participate in biomedical research to consider the implications and possible applications of their work and to weigh carefully in the balance the pursuit of scientific knowledge with their ethical responsibilities to society.



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

GUIDELINES FOR GOOD PRACTICE IN THE HEALTH CARE PROFESSIONS

ETHICAL GUIDELINES ON SOCIAL MEDIA

EDITED BY THE HUMAN RIGHTS, ETHICS AND PROFESSIONAL PRACTICE

BOOKLET 16

2019

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300

Fax: (012) 328 4863

E-mail: hpcs@hpcs.co.za

Website: <http://www.hpcs.co.za>

THE INTENT OF PROFESSIONAL GUIDELINES

Practicing as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, the practice of health care professions is a moral enterprise. The HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health care practitioner" in these guidelines refers to persons registered as such with the HPCSA].

TABLE OF CONTENTS

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

ACKNOWLEDGEMENTS

- 1 ABOUT THESE GUIDELINES**
- 2 INTRODUCTION**
- 3 DEFINITION OF SOCIAL MEDIA**
- 4 CONTEXT IN RELATION TO HPCSA**
- 5 WHO NEEDS TO USE THESE GUIDELINES?**
- 6 OBLIGATIONS IN RELATION TO SOCIAL MEDIA**
- 7 PATIENT CONFIDENTIALITY AND PRIVACY**
- 8 THE PRACTITIONER-PATIENT RELATIONSHIP**
- 9 THE HEALTH PRACTITIONER'S IMAGE**
- 10 CONFLICT OF INTEREST**
- 11 PRECAUTIONARY MEASURES WHEN USING SOCIAL MEDIA**
- 12 REFERENCES**

The Health Professions Council of South Africa wishes to thank the following persons for their contributions towards the compiling of these guidelines:

- Dr N Tsotsi for the first draft, and Ms Nerissa Naidoo and Prof DJ McQuoid-Mason for the second and third drafts.
- Prof A Dhai for reviewing the first and third drafts.
- The Committee for Human Rights, Ethics and Professional Practice of the Health Professions Council of South Africa for initiating and advising the review process:
Dr S Balton (Chairperson), Prof D J. McQuoid-Mason, Dr N Tsotsi, Prof B Pillay, Prof N Gwele, Prof N Mekwa, Prof S Hanekom.
- Adv Mathibeli as the legal advisor, Ms N Manciya as Committee coordinator and Mr N Sipeka as the Council secretariat.

The guideline was developed to help health practitioners understand their obligations when using social media. The guideline applies to all health practitioners registered with the Health Professions Council of South Africa.

2 INTRODUCTION

- 2.1 The use of social media is expanding rapidly as individuals and organisations are embracing user-generated content through social networks, internet forums and personal blogs.
- 2.2 Irrespective of whether online content is accessible to the public at large or is limited to specific health practitioners, there is a need to maintain high professional and ethical standards in using social media.
- 2.3 Health professionals need to be aware that there are potential risks involved in the sharing of information via social media, even if the consequences are unintended.
- 2.4 The General Ethical and Professional Rules of Conduct set out in Booklet 2: Ethical Rules of Conduct for Practitioners Registered Under the Health Professions Act, 1974 as published under Government Notice R7171 in *Government Gazette* 29079 of 4 August 2006 and as amended.

3 DEFINITION OF SOCIAL MEDIA

- 3.1 Social media describes the online tools and electronic platforms that people use to share content such as opinions, information, photos, videos and audio.
- 3.2 Social media includes social networks (e.g. Facebook, Twitter, WhatsApp and LinkedIn), content-sharing platforms (e.g. YouTube and Instagram), personal and professional blogs (including email, SMS, electronic journals as well as those published anonymously), internet discussion forums, and the comment sections of websites.

4 CONTEXT IN RELATION TO HPCSA

- 4.1 A key objective of the HPCSA and its Professional Boards is to guide the profession and protect the public.
- 4.2 Health practitioners may find social media beneficial as it allows them to keep updated on the latest healthcare developments through reputable user-generated content, build a professional support network as well as communicate and share health-related information with the public and other health practitioners.
- 4.3 These guidelines must be read in conjunction with the other HPCSA Ethical Guidelines Booklets and other applicable publications.

5 OBLIGATIONS IN RELATION TO SOCIAL MEDIA

- 5.1 Just as with all aspects of professional behaviour, health practitioners should be aware of their obligations under the HPCSA Ethical and Professional Rules, the Professional Board's scope of practice and other relevant legislation, such as the Promotion of Access to Justice Act 3 of 2000, the Protection of Personal Information Act 4 of 2013, and the common law.
- 5.2 There are ethical obligations and responsibilities imposed on health practitioners regarding their relationships with their patients and each other, such as those set out in Booklet 1 *General Ethical Guidelines for Health Care Professionals* and Booklet 5 *Confidentiality: Protecting and Providing Information*.
- 5.3 Obligations relating to the electronic storage and transmission of patient and client data for professional purposes are found in Booklet 10 *General Ethical Guidelines for Good Practice in Telemedicine*.

6 PATIENT CONFIDENTIALITY AND PRIVACY

- 6.1 All patients are entitled to privacy and confidentiality, which is enshrined under the human right to privacy in the South African Constitution and the National Health Act.
- 6.2 Disclosure of a patient's information may only be in accordance with a court order, patients consent and in terms of the law.

- 6.2.1 Health practitioners can share confidential information with other members of the health care team involved in the patient's care and with individuals who have the patient's consent.
- 6.2.2 Health practitioners can also share information if it is justified in the public interest, or if failure to do so will result in harm to the patient.
- 6.3 Health practitioners must obtain the written consent of the patient before publishing information (e.g. case histories and photographs) about them in media to which the public has access, whether or not the health care practitioner believes the patient can be identified by the data.
- 6.4 If the patient is a minor under the age of 12 years old, the health care practitioner will require the written consent of the patient's parent or guardian and assent of the minor.
- 6.5 Health practitioners sharing information or data for the sake of diagnosis, treatment or education and training through social media must ensure that the recipient of the information is not able to identify the patient from the data disclosed.
 - 6.5.1 Health practitioners must ensure that the recipient of patient information via social media understands that such information is given to them in confidence, which they must respect.
- 6.6 Disclosure of information on social media must be kept to the minimum necessary in order to protect the rights of patients.
- 6.7 Health practitioners must be aware that there is always a risk that the information can be disseminated, even in so-called "invisible" groups, (i.e. people you do not know are reading the information or who you did not know could read the information).
- 6.8 The obligation to keep patient information confidential remains even after the patient dies.

7 THE PRACTITIONER-PATIENT RELATIONSHIP

- 7.1 Interaction between health practitioners and their patients on social media can blur the boundaries of the professional practitioner-patient relationship.
- 7.2 Health practitioners are advised not to interact with patients via social media platforms as a failure to maintain strictly professional relationships with patients could result in other ethical dilemmas.
- 7.3 The Protection of Personal Information Act outlaws the acquisition of data about an individual's health or sex life outside the healthcare setting, and by having access to patients' social media profiles, health care practitioners may find themselves privy to personal patient information that has not been shared in the healthcare setting.
- 7.4 Health practitioners may choose to share personal information about themselves with their patients during face-to-face consultations, but social media does not offer a similar level of control over the extent and type of content shared.
- 7.5 If the health practitioner performs a non-medical role in their community, maintaining appropriate professional boundaries may be difficult as they may receive requests on social media from patient's they know in a non-professional capacity. In these instances, health practitioners should consider the circumstances and implications before accepting these requests.
- 7.6 Should the health practitioner receive an inappropriate message from a patient via social media, they should politely re-establish professional boundaries and explain their reasons for doing so.
- 7.7 Except in an emergency or life-threatening situation, if a patient is seeking health care advice over social media, the health care practitioner should politely request them to set up an appointment in-person.
- 7.8 If a patient persists in contacting the health practitioner, the practitioner should keep a log of all contacts and seek advice from the HPCSA.
- 7.9 Providing health advice over social media to individuals with whom the health practitioner does not have a practitioner-patient relationship is discouraged and should be done with the outmost discretion.
- 7.10 If health advice is shared online, it must be evidence based , scientifically sound and generic and the recipient must be directed to consult with a health practitioner in person before following through.
- 7.11 Health practitioners should separate their professional and personal social media accounts to help maintain the appropriate professional boundaries.

8 THE HEALTH PROFESSION'S IMAGE

- 8.1 If the health care practitioner uses social media in their personal capacity, their online activity may nevertheless bring the profession into disrepute.
- 8.2 The media routinely monitor online activity to research stories or potential stories. Information posted online may be disseminated, whether intended or not, to a larger audience, and may be taken out of context.
- 8.3 Content posted on social media may also harm the health practitioner's employability and recruitment, limiting professional development and advancement. Employers often monitor the social media profiles of prospective employees, and are known to turn away applicants based on questionable digital behaviour.
- 8.4 Social media activities health practitioners should avoid for example include:
- 8.4.1 Taking photographs during surgery and other forms of care or treatment;
 - 8.4.2 Making unsubstantiated negative comments about individuals or organisations;
 - 8.4.3 Making informal and derogatory comments about patients;
 - 8.4.4 Making comments that can be perceived as racist, sexist, homophobic or otherwise prejudiced, even if meant in jest or as satire.
- 8.5 Health practitioners may engage fully in debates on health matters, however they must be aware that the laws regarding defamation, hate speech and copyright also extend to content shared via social media.
- 8.6 Health practitioners must not post their opinions on the probity, skill or professional reputation of their colleagues on social media, lest the public lose faith in the health care profession.
- 8.7 Online relationships between practitioners of varying levels of training should only be initiated upon consideration of the purpose of the relationship. In the case of senior staff receiving social media requests from students (or vice versa), the purpose might be mentorship, research or career advice. Regardless of intent, the traditional boundaries of the trainee-teacher relationship apply even in interactions via social media. These boundaries also extend to staff and other health practitioners.
- 8.8 If a colleague makes derogatory or inappropriate comments on social media, health practitioners are advised to bring it to their attention discreetly, and not to engage or respond publicly on the social media platform.

- 8.9 Health practitioners are advised to include disclaimers in their social media profiles, indicating that the views expressed therein are their own and not those of the health profession or the health establishment they represent. However, this does not absolve the health care practitioner from the above rules.

9 CONFLICTS OF INTEREST

- 9.1 Social media is also a popular tool for the advertisement and promotion of goods and services, with the growing online market being one of the most emphasised in business practice.
- 9.2 When using social media, even if via personal or anonymous blogs, health care practitioners must comply with the HPCSA rules on advertising practice, (including not engaging in active or passive touting and canvassing or allowing others to do so on their behalf), and must make sure that they declaring their financial interests in hospitals (see Booklet 2 *Ethical and Professional Rules of the Health Professions Council of South Africa* and Booklet 11 *Guidelines on Overservicing, Perverse Incentives and Related Matters*).
- 9.3 Touting involves drawing attention to one's professional goods or services by offering guarantees or benefits that fall outside one's scope of practice. An example is advertising free WiFi services to patients while waiting for their consultations.
- 9.4 Canvassing involves the promotion of one's professional goods and services by drawing attention to one's personal qualities, superior knowledge, quality of service, professional guarantees, or best practice. An example of canvassing is a health care practitioner declaring on social media or posting patient reviews that state he or she is 'the best health care practitioner in the country'.
- 9.5 Health practitioners may not advertise, endorse or encourage the use of any hospital, medicine or health-related product on social media in a manner that unfairly promotes the practice of a particular health practitioner or establishment for the purposes of financial gain or other valuable consideration.
- 9.6 A failure to follow these guidelines when using social media will undermine public trust in the health profession.

10 PRECAUTIONARY MEASURES WHEN USING SOCIAL MEDIA

- 11.1 Health practitioners must be aware that, even with a pseudonym, anonymity on social media platforms is never guaranteed. The identity and location of the user can be traced through their linked accounts or IP address.
- 11.2 If health practitioners use social media in their personal capacity, they are advised to adjust their privacy settings to restrict public access. However, even with advanced security measures and end-to-end encryption, complete privacy on social media cannot be guaranteed. There is always the risk that the content can be shared beyond the scope of the health practitioner's personal network.
- 11.3 Once content is shared online, it is difficult to remove, and health practitioners must use social media on the understanding that the information they post will remain on the internet permanently.
- 11.4 Even if a health practitioner deletes a post on a social media site, this does not necessarily mean the content has been removed. Content may be copied or reproduced by other users before it has been deleted, and many websites and internet browsers use cache and cookie systems that inconspicuously store data.
- 11.5 Health practitioners should avoid using social media when stressed, tired, upset or under the influence of alcohol.
- 11.6 Health practitioners are advised to err on the side of caution when using social media. If uncertain about whether it is ethically and legally permissible to share particular content via social media, it is best not to do so until advice has been obtained.

12 REFERENCES

- 12.1 American Medical Association Policy: Professionalism in the Use of Social Media (2012) <https://mededu.jmir.org/article/downloadSuppFile/4886/28296>.
- 12.2 British Medical Association: Social media, ethics and professional (2017) <https://www.bma.org.uk/advice/employment/ethics/social-media-guidance-for-doctors>.
- 12.3 General Medical Council: Doctors Use of Social Media (2013) <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/doctors-use-of-social-media>.
- 12.4 South African Medical Association: Guidelines for doctors using social media (2015) <https://www.samedical.org/files/Guideline%20for%20Drs%20Using%20Social%20Media%20febr015.pdf>.

- 12.5 Grobler C, Dhai A. Social Media in the healthcare context: Ethical challenges and recommendations. *S Afr J BL* 2016; 9(1): 22-25.
- 12.6 National Department of Health. *National Policy Framework and Strategy on Palliative Care 2017-2022*.



COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

ETHICAL GUIDELINES ON PALLIATIVE CARE

EDITED BY THE HUMAN RIGHTS, ETHICS AND PROFESSIONAL PRACTICE

BOOKLET 17

2019

Health Professions Council of South Africa
Post Office Box 205
Pretoria 0001

Telephone: (012) 338 9300

Fax: (012) 328 4863

E-mail: hpcs@hpcs.co.za

Website: <http://www.hpcs.co.za>

THE INTENT OF PROFESSIONAL GUIDELINES

Practicing as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, the practice of health care professions is a moral enterprise. The HPCSA presents the following ethical guidelines to guide and direct the practice of health care practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "health practitioner" in these guidelines refers to persons registered as such with the HPCSA].

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

TABLE OF CONTENTS

ACKNOWLEDGEMENTS

- 1 PREAMBLE**
- 2 WHEN PALLIATIVE CARE IS USED**
- 3 WHY PALLIATIVE CARE IS USED**
- 4 WHO PROVIDES PALLIATIVE CARE?**
- 5 WHERE PALLIATIVE CARE IS USED**
- 6 HOW PALLIATIVE CARE IS USED**
- 7 PATIENT AUTONOMY AND PALLIATIVE CARE**
- 8 BENEFICENCE AND PALLIATIVE CARE**
- 9 NON-MALEFICENCE AND PALLIATIVE CARE**
- 10 JUSTICE OR FAIRNESS AND PALLIATIVE CARE**
- 11 REFERENCES**

ACKNOWLEDGEMENTS

The Health Professions Council of South Africa wishes to thank the following persons for their contributions towards the revision of the guidelines:

- Ms. Nerissa Naidoo and Prof D J. McQuoid-Mason for drafting the document, and Prof A Dhai and the SA Hospice Association for reviewing it.
The Committee for Human Rights, Ethics and Professional Practice of the Health Professions Council of South Africa for initiating and advising the review process: Dr S Balton (Chairperson), Prof D J. McQuoid-Mason, Dr N Tsotsi, Prof B Pillay, Prof N Gwele, Prof N Mekwa, Prof S Hanekom.
- . Adv Mathibeli as the legal advisor, Ms N Manciya as Committee coordinator and Mr N Sipeka as the Council secretariat.

1 PREAMBLE

- 1.1 The World Health Organisation (WHO) defines palliative care as ‘an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual’.
- 1.2 Palliative care:
- 1.2.1 provides relief from pain and other distressing symptoms;
 - 1.2.2 affirms life and regards dying as a normal process;
 - 1.2.3 intends neither to hasten or postpone death;
 - 1.2.4 integrates the psychological and spiritual aspects of patient care;
 - 1.2.5 offers a support system to help patients live as actively as possible until death;
 - 1.2.6 offers a support system to help the family cope during the patient’s illness and in their own bereavement;
 - 1.2.7 uses a team approach to address the needs of patients and their families, including bereavement counselling, if indicated;
 - 1.2.8 will enhance quality of life, and may also positively influence the course of illness;
 - 1.2.9 is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.’
- 1.3 With the spread of HIV, South Africa shoulders a significant disease burden, and the Department of Health’s *National Policy Framework and Strategy on Palliative Care 2017–2022* acknowledges the importance of integrating palliative care as an essential component of health service delivery.

2 WHEN IS PALLIATIVE CARE PROVIDED

- 2.1 Palliative care is provided to those living with and dying from any advanced, progressive and incurable condition regardless of age or setting.
- 2.2 Palliative care is provided throughout the journey, from diagnosis to end of life.

- 2.3 As the patient's disease progresses, the need for palliative care will increase and the level of curative treatment will decrease.
- 2.4 The WHO recognises that palliative care is required for a wide range of diseases, including but not limited to:
- 2.4.1 Cardiovascular disease;
 - 2.4.2 Cancer;
 - 2.4.3 Chronic respiratory diseases;
 - 2.4.4 AIDS;
 - 2.4.5 Diabetes;
 - 2.4.6 Kidney failure;
 - 2.4.7 Chronic liver disease;
 - 2.4.8 Multiple sclerosis;
 - 2.4.9 Parkinson's;
 - 2.4.10 Rheumatoid arthritis;
 - 2.4.11 Neurological disease;
 - 2.4.12 Dementia;
 - 2.4.13 Congenital anomalies;
 - 2.4.14 Drug-resistant tuberculosis

3 WHY IS PALLIATIVE CARE PROVIDED

- 3.1 Palliative care is recognised by the United Nations as part of the human right to health.
- 3.2 The goal of palliative care is the achievement of the best possible quality of life for patients and their families, even if life expectancy is short.
- 3.3 Palliative care is an extension of the South African Constitutional rights of human dignity and access to healthcare.
- 3.4 The Constitution also guarantees the right to basic healthcare for children which includes the provision of paediatric palliative care, and not merely access to such care, as is the case with adults.
- 3.5 Evidence suggests that palliative care can reduce unnecessary hospitalisation and use of health care services, which lessens the costs of the health system.

4 WHO PROVIDES PALLIATIVE CARE?

- 4.1 Palliative care is provided by all health practitioners and other health care professionals working with people with life-threatening conditions.

- 4.2 Health practitioners providing palliative care should possess the requisite knowledge, skills and attitudes to meet the physical, psychological, practical, social and spiritual needs of their patients.
- 4.3 Health practitioners providing palliative care should keep their skills up to date.
- 4.4 As a result of the current inadequate provision of palliative care services in the country, the National Department of Health has developed a strategy to increase the scope of palliative care services in its *National Policy Framework and Strategy on Palliative Care 2017-2022*.
- 4.5 It is imperative that all healthcare professionals play an advocacy role on the importance of palliative care services in the public health sector and for palliative care to be included in the curriculum of health practitioners.

5 WHERE IS PALLIATIVE PROVIDED

- 5.1 Palliative care can be provided in public, private facilities and patient's homes.
- 5.2 According to the National Department of Health National Policy Framework and Strategy on Palliative Care the different palliative care service delivery settings, are:
 - 5.2.1 Home-based palliative care;
 - 5.2.2 Mobile outreach services;
 - 5.2.3 Outpatient care;
 - 5.2.4 Inpatient palliative care facilities;
 - 5.2.5 Hospital based palliative care teams;
 - 5.2.6 Day care palliative services;
 - 5.2.7 Frail care and other care homes;
 - 5.2.8 Workplace programs; and
 - 5.2.9 Correctional services.

6 HOW PALLIATIVE CARE IS USED

- 6.1 Health practitioners must deliver care in a manner that upholds these principles, and the rights and values of the patient and their family, even in the midst of a dehumanising environment or in noisy facilities/areas”
- 6.2 Health practitioners providing palliative care should apply the bioethical principles of autonomy, beneficence, non-maleficence and justice that require respect for the worth, dignity and human rights of their patients when managing them.
- 6.3 Patients and their families faced with life-threatening illnesses, are likely to be vulnerable and anxious during this time, health practitioners providing palliative care will find the bioethical principles helpful in guiding decision-making.
- 6.4 Health practitioners must establish trust in the patient and their family through availability, listening, providing honest answers, and having a non-judgmental attitude.
- 6.5 In administering palliative care, health practitioners should also adhere to the HPCSA’s general ethical guidelines and the National Department of Health’s *National Policy Framework and Strategy on Palliative Care 2017–2022*.

7 PATIENT AUTONOMY AND PALLIATIVE CARE

7.1 MEANING OF PATIENT AUTONOMY

- 7.1.1 Patient autonomy recognises the ability of patients to make decisions for themselves regarding palliative care, and is in accordance with the constitutional rights to human dignity and bodily and psychological integrity.
- 7.1.2 Patient autonomy presumes that patients have the required information and capacity to make rational decisions about palliative care and that the circumstances allow them to give an informed consent.
- 7.1.3 When obtaining informed consent from patient’s health practitioners providing palliative care must comply with the National Health Act 61 of 2003 and the HPCSA’s guidelines on *Seeking Patients’ Informed Consent: The Ethical Considerations* (Booklet 9).

7.2 CAPACITY TO CONSENT TO PALLIATIVE CARE

- 7.2.1 Health practitioners providing palliative care should assume that every mentally competent adult patient and every sufficiently mature child patient over the age of 12 years have legal capacity to consent to, or oppose, medical interventions - unless it is shown that they clearly cannot understand the information given to them.
- 7.2.2 It is for the patient, and not the health practitioner providing palliative care, to determine what is in the patient's best interests.
- 7.2.3 Although health practitioners providing palliative care may recommend a course of treatment, they may not pressurize or manipulate the patient into accepting their advice.
- 7.2.4 Health practitioners providing palliative care must understand and respect that a patient's decision-making may be guided by values, customs and beliefs different from the practitioner's.
- 7.2.5 If a mentally and legally competent patient, who is fully informed of the benefits and risks of treatment, consents to or refuses a particular course of treatment, their decision must be respected, even if the health practitioner providing palliative care believes it will result in serious harm or even death.
- 7.2.6 Respecting patient autonomy, however, does not mean that patients are entitled to illegal, unethical or medically inappropriate treatment simply because they have requested it.
- 7.2.7 Health practitioners providing palliative care should only recommend and provide treatment options that are both scientifically grounded, and are, in their best medical judgement, reasonably expected to yield the intended benefits.
- 7.2.8 Should a patient request illegal, unethical or medically inappropriate treatment, the health practitioner providing palliative care should reassure them and their family of the sound treatment options available to the patient - subject to consent by the latter or his or her surrogate.

7.3 ADVANCED PALLIATIVE CARE PLANNING

- 7.3.1 Patient autonomy includes the need to protect patients with diminished autonomy.
- 7.3.2 Health practitioners providing palliative care should encourage competent patients to indicate their wishes regarding treatment options in an advance directive, such as a living will, and in such a document or a written nomination of a surrogate in terms of the National Health Act, to mandate a person to make decisions on their behalf if they become incapacitated.
- 7.3.3 An advance directive helps ensure consideration of the patient's values and preferences, even when they lack the capacity to express them.
- 7.3.4 Health practitioners providing palliative care should record any conversations with a competent patient regarding their goals for care in their medical records, and should review such goals regularly and as circumstances change.
- 7.3.5 The advance directive or other records of the patient's wishes should be kept inside the patient's file, with stickers indicating that the advance directive is available for ease of reference.
- 7.3.6 The *Patient's Rights Charter* introduced by the National Department of Health requires patients to advise their healthcare provider of their wishes regarding death, and to take care of any medical records in their possession – see *HPSCA National Patient's Rights Charter* (Booklet 3).
- 7.3.7 An advance directive should include the following:
- 7.3.7.1 the patient's wishes and preferences with regard to future treatment;
 - 7.3.7.2 any beliefs or values that may influence the patient's decisions and preferences;
 - 7.3.7.3 the family members or surrogates that should be involved in decision-making;
 - 7.3.7.4 any interventions that should be considered and implemented in case of emergency, such as CPR;
 - 7.3.7.5 the patient's preferred place of care; and
 - 7.3.7.6 the patient's need for religious, spiritual, and other personal support.
- 7.3.8 As is the case with life-threatening illness, towards the end-of-life, it is not uncommon for a patient's mental capacity to be impaired.
- 7.3.9 When a patient becomes mentally incompetent, and an advance directive is available, health practitioners providing palliative care should give effect to the patient's wishes – provided that the directive is applicable to the present circumstances and represents the patient's current wishes.

- 7.3.10 If no advance directive is available, and no surrogate has been appointed, the health practitioner providing palliative care must, in consultation with the patient's family, determine the treatment option that is in the patient's best interest.
- 7.3.11 In determining an incapacitated patient's best interests during the decision-making process, the health practitioner providing palliative care must consider:
- 7.3.11.1 the medically appropriate treatment options available;
 - 7.3.11.2 any previous requests of the patient when he or she was mentally competent;
 - 7.3.11.3 what the practitioner knows about the background and preferences of the patient, in consultation with the patient's healthcare team;
 - 7.3.11.4 information regarding the patient's values, beliefs and preferences from third parties who may have other knowledge of the patient due to their relationship (e.g. a parent, sibling, child or spouse);
 - 7.3.11.5 where more than one treatment option is reasonably in the patient's best interests, the practitioner must, in consultation with the patient or the patient's surrogate, choose the option that least restricts the patient's future choices.
- 7.3.12 The health practitioner providing palliative care must take appropriate action in the case of illegal, unethical or inappropriate behaviour that jeopardises the best interests of the patient.

7.4 COMMUNICATION

- 7.4.1 Health practitioners providing palliative care must communicate effectively and timeously with the patient and their family, and the rest of the palliative care team.
- 7.4.2 Health practitioners providing palliative care must take into account the emotional toll that the circumstances regarding the use of palliative care may have on the patient and their family, and should communicate with them in an empathic and understandable manner.
- 7.4.3 If a patient's communication skills are compromised by their illness, health practitioners providing palliative care must communicate with the patient through verbal and non-verbal means.
- 7.4.4 Irrespective of the patient's level of consciousness, health practitioners providing palliative care should communicate any proposed interventions to the patient, based on the understanding that hearing is the last sense to die.

8 BENEFICENCE AND PALLIATIVE CARE

8.1 MEANING OF BENEFICENCE

- 8.1.1 The principle of beneficence requires the health practitioner providing palliative care to do good for their patients.
- 8.1.2 The health practitioner providing palliative care must weigh up the costs, risks and benefits of particular forms of palliative care and recommend those that are most beneficial to the patient, while leaving the final decision to the patient or their surrogate.
- 8.1.3 From the moment of diagnosis of a life-threatening condition, the health practitioner providing palliative care must monitor the patient and keep abreast of relevant medical advancements, and ensure that their knowledge and understanding of palliative care is up to date.
- 8.1.3 If the health practitioner providing palliative care is not able to manage severe or refractory symptoms, it is important for such practitioner to refer the patient to a health practitioner who is qualified to do so.

8.2 WITHHOLDING OR WITHDRAWAL OF TREATMENT

- 8.2.1 The health practitioner providing palliative care is required to balance the intended benefits of palliative care against the risks and burdens of treatment.
- 8.2.2 In some instances, the quality of life which follows palliative treatment may raise questions as to whether such treatment is in the best interests of the patient.
- 8.2.3 Treatment can legally and ethically be withheld or withdrawn if the patient refuses further treatment, further treatment is futile, or if it is no longer in the patient's best interests (e.g. when treatment merely prolongs the dying process).

- 8.2.4 The decision to withhold or withdraw treatment must not be taken lightly, and must be considered by the health practitioner providing palliative care in consultation with the patient and their family.
- 8.2.5 When the possibility of withholding or withdrawal of treatment arises, the health practitioner providing palliative care should discuss with the patient and their family, arrangements for basic care and other appropriate treatments.
- 8.2.6 At end-of-life, discussions about withholding or withdrawal of treatment should include plans to manage the final stages of the lives of patients, before they are incapacitated, and include personal matters such as wills, as well as any other concerns that patients believe are important to ensure that they die with dignity.
- 8.2.7 When dealing with end-of-life decisions health practitioners providing palliative care must approach the withholding or withdrawal of treatment in a manner consistent with the HPSCA's *Guidelines for the Withholding and Withdrawal of Treatment* (Booklet 7).

9 NON-MALEFICENCE AND PALLIATIVE CARE

- 9.1 Non-maleficence requires health practitioners providing palliative care not to harm their patients and complements beneficence and the balancing of risks and benefits.
- 9.2 Euthanasia and doctor-assisted suicide are often perceived as inconsistent with the principle of non-maleficence.
- 9.3 Euthanasia and doctor-assisted suicide are presently prohibited under South African law, and the courts frequently do not distinguish between the two when it comes to culpability.
- 9.4 Euthanasia is the employment of any medical intervention primarily aimed at ending a patient's life (e.g. giving a patient lethal drug or injection).
- 9.5 Doctor-assisted suicide occurs when the health practitioner provides the means necessary to enable the patient to end their own life (e.g. handing a patient a lethal drug or prescribing a lethal drug for a patient).
- 9.5 At present, South African courts have acknowledged that both euthanasia and doctor-assisted suicide are fundamentally incompatible with a practitioner's role as a healer, and a practitioner guilty of either is regarded as having acted unethically and unlawfully.

- 9.6 Due to the stress of extreme pain and the prospect of facing a life-threatening illness, a patient may request a health practitioner providing palliative care to end their life.
- 9.7 The role of the health practitioner providing palliative care in this instance is to discuss the concerns and fears that have led to the patient's request, and to provide alternate approaches to address these issues.
- 9.8 When medical treatment relieves suffering - but has the effect of accelerating the dying process - the health practitioner providing palliative care must consider whether the palliative benefits justify the shortened life expectancy before pursuing that course of treatment.
- 9.9 Palliative care treatment where life is shortened as a side effect, is not regarded as unlawful or unethical – provided the patient or their surrogate has given informed consent.

10 JUSTICE OR FAIRNESS AND PALLIATIVE CARE

- 10.1 The World Health Organisation (WHO) states that 'palliative care needs to be provided in accordance with the principles of universal health coverage'.
- 10.2 This means that everyone, 'irrespective of income, disease type or age, should have access to a nationally determined set of basic health services, including palliative care' and is consistent with the South African Constitution.
- 10.3 The WHO also states that 'financial and social protection systems need to take into account the human right to palliative care for poor and marginalized population groups'.
- 10.4 Palliative care should be available to all patients from birth until death, and should be accessible at all levels of the health care service and this is what the National Department of Health's *National Policy Framework and Strategy on Palliative Care 2017–2022* aspires to do.
- 10.5 Health practitioners providing palliative care must treat patients equally and without discrimination.
- 10.6 According to the National Department of Health's *National Policy Framework and Strategy on Palliative Care 2017–2022* health practitioners providing palliative care must give special consideration to the following groups of people in their provision of palliative care services:

- 10.6.1 Persons with disabilities;
 - 10.6.2 Children (including neonates and adolescents);
 - 10.6.3 Older persons including those living in residential care settings and frail care facilities;
 - 10.6.4 Asylum seekers and refugees;
 - 10.6.5 Inmates of correctional services; and
 - 10.6.6 Persons in long term care facilities such as TB and psychiatric hospitals or residential care facilities.
- 10.6 Palliative care practitioners should use the country's limited health care resources responsibly, fairly and effectively to ensure all patients receive appropriate palliative care.

11 REFERENCES

- 11.1 National Department of Health. *National Policy Framework and Strategy on Palliative Care 2017-2022*.
- 11.2 National Health Service Scotland. *Scottish Palliative Care Guidelines* (2014). <http://www.palliativecareguidelines.scot.nhs.uk/guidelines/about-the-guidelines.aspx>.
- 11.3 American Medical Association. *Opinions on Caring for Patients at End of Life* (2016). <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-5.pdf>.
- 11.4 General Medical Council. *Treatment and Care towards End of Life: Good Practice in Decision-Making* (2010). <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/treatment-and-care-towards-the-end-of-life>.
- 11.5 Irish National Clinical Programme for Palliative Care: Palliative Care Needs Assessment Guidance (2014). <https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/palliative-care-needs-assessment-guidance.pdf>.
- 11.6 Republic of Kenya Ministry of Health. *National Palliative Care Guidelines* (2013). <http://kehpc.org/wp-content/uploads/National-Palliative-Care-Guidelines-02.10.pdf>.
- 11.7 Australian Medical Association. *Position Statement on End of Life Care and Advance Care Planning* (2014). <https://ama.com.au/position-statement/end-of-life-care-and-advance-care-planning-2014>.
- 11.8 Canadian Medical Association. *Palliative Care National Call to Action* (2015). <https://www.cma.ca/Assets/assets-library/document/en/advocacy/palliative-care-report-online-e.pdf>.