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HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

GUIDELINES FOR GOOD PRACTICE

IN THE HEALTHCARE PROFESSIONS

GENERAL ETHICAL GUIDELINES FOR THE

HEALTHCARE PROFESSIONS

BOOKLET 1

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THE SPIRIT OF PROFESSIONAL GUIDELINES

Good clinical practice is based on a trust relationship between patients and healthcare professionals. Being a good healthcare practitioner requires a life-long commitment to sound professional and ethical practice and an overriding dedication to the interests and wellbeing of one's fellow human beings and society. This makes the practice in the healthcare profession a moral enterprise. It is in this spirit that the HPCSA presents the following ethical guidelines to guide and direct the practice of healthcare practitioners. These guidelines are an integral part of the standards of professional conduct against which professional conduct is evaluated.

[Note: The terms "healthcare practitioner", "practitioner" and "healthcare professional" in these guidelines refer to persons registered with the HPCSA].

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1. INTRODUCTION

- 1.1Being registered as a healthcare professional with the Health Professions Council of South Africa (HPCSA) confers one the right and privilege to practise a profession. Correspondingly, practitioners have moral and ethical duties to others and society in general. These duties are, in part, in keeping with the principles of the South African Constitution (Act No. 108 of 1996) and the obligations imposed on healthcare professionals by law.
- 1.2 This first booklet on general ethical guidelines contains value-oriented principles and expresses the most honourable ideals to which members of the healthcare profession should subscribe in terms of their conduct.
- 1.3 Specific ethical guidelines and rules are derived from these general ethical guidelines. They offer more precise guidance and direction for action in concrete situations.
- 1.4 It is impossible, however, to develop a complete set of specific ethical prescriptions applicable to all conceivable real-life situations. In many specific or unique settings, healthcare professionals will have to work out for themselves what course of action is most appropriate from an ethical standpoint. This requires ethical reasoning.
- 1.5 This booklet lists core ethical values and standards that underpin professional and ethical practice in the healthcare professions and gives a concise explanation of how practical decisions should be made through ethical reasoning. It also explains what a duty is, and catalogues the general ethical duties of healthcare professionals

Note: Environmental Health Practitioners do not see patients]

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2. CORE ETHICAL VALUES AND STANDARDS FOR GOOD PRACTICE

- 2.1 Maintenance of good professional practice is grounded in core ethical values and standards the latter are the directives that follow the core values.
- 2.2 On occasion, the demands of these core values and standards may clash, thus placing competing demands on healthcare practitioners. The only way to address such clashes is through ethical reasoning.
- 2.3 The core ethical values and standards required of healthcare practitioners include the following:
- 2.3.1 Respect for persons: Health are practitioners must respect patients as persons, and acknowledge their intrinsic worth, dignity, and sense of value.
- 2.3.2 Best interests or well-being of patients:
- 2.3.2.1 Beneficence: Healthcare practitioners must act in the best interests of patients even when the interests of the latter conflict with their own personal self-interest.
- 2.3.2.2 Non-maleficence: Healthcare practitioners must 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 Human rights: Healthcare practitioners must recognise and respect the human rights of all individuals.
- 2.3.4 Autonomy: Healthcare practitioners must honour the right of patients to self-determination, which allows them to make their own informed choices, and to live their lives by their own beliefs, values and preferences.
- 2.3.5 Integrity: Healthcare practitioners should incorporate these core ethical values and standards as the foundation for their character and practice.
- 2.3.6 Truthfulness: Healthcare practitioners must regard the truth and truthfulness as the basis of trust in their relationships with patients.
- 2.3.7 Confidentiality: Healthcare practitioners must treat personal or private information as confidential in professional relationships with patients unless overriding reasons confer an ethical or legal obligation to disclosure.
- 2.3.8 Compassion: Healthcare 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.
- 2.3.9 Tolerance: Healthcare practitioners must respect the rights of people to have different ethical beliefs as these may arise from deeply held personal, religious or cultural convictions.
- 2.3.10 Justice: Healthcare practitioners must treat all individuals and groups in an impartial, fair and just manner.
- 2.3.11 Professional competence and self-improvement: Healthcare practitioners must continually endeavour to attain the highest level of knowledge and skills required within their area of practice.

2.3.12 Community: Healthcare practitioners should strive to contribute to the betterment of society in accordance with their professional abilities and standing in the community.

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3. HOW TO RESOLVE ETHICAL DILEMMAS

- 3.1The core values and standards referred to above are the foundation that grounds the general ethical guidelines in these booklets. Generally, the guidelines may be applied to many different settings. Questions may arise regarding healthcare practitioners' best use of these guidelines to make practical decisions or choices about the provision of healthcare. For example, how does a guideline apply in a specific case? And how do healthcare practitioners handle difficult situations where two (or more) principles appear to be in conflict?
- 3.3This requires ethical reasoning that in general, proceeds using the following steps:
- 3.3.1 Formulate the problem: Determine whether the issue is an ethical one.

- 3.3.2 Gather information: All the relevant information should be collected including clinical, personal and social data. Seek information form authoritative sources such as these guidelines, practitioner associations, respected colleagues and also incorporate the experience of practitioners generally when they deal with such matters.
- 3.3.3 Consider the available options: Consider the potential solutions and the principles and values that each of these uphold.
- 3.3.4Make an ethical (and moral) assessment: The ethical content of each option must be determined 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?
- 3.3.4.3What are the weaknesses of each option?
- 3.3.4.4How would the healthcare practitioner himself or herself want to be treated or managed under similar circumstances. –
- 3.3.4.5How does the healthcare practitioner expect a patient would want to be treated?
- 3.3.5Discuss your proposed solution with those it may affect.
- 3.3.6Act on your decision with sensitivity to others who may be affected.
- 3.3.7Regularly re-evaluate your decision and be prepared to act differently in future.
- 4. WHAT IT MEANS TO HAVE A DUTY
- 4.1 Ethical guidelines and legal prescripts express duties. A duty is an obligation to do or refrain from doing something in the personal, social, professional, or political spheres of people's lives.
- 4.2 Having a duty to another person it means a practitioner is bound to that person in some respect and for some reason. The practitioner owes that person something, while he or she holds a corresponding right or claim against the practitioner. In other words, to have a duty asks the question "What do I owe others?" while having a right asks the question "What do others owe me?"

- 4.3 An example of a right with a corresponding duty is the following: Suppose a healthcare practitioner reaches an agreement with a colleague that the latter will do a locum for she/him while she/he is away: The colleague has a duty to do the locum and the healthcare practitioner has a right to the colleague's services. At the same time the colleague has a right to fair remuneration and the healthcare practitioner has a duty to compensate her/him.
- 4.6 Healthcare practitioners fulfil multiple roles and duties:
- 4.6.1 As human beings they have "natural duties", 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, healthcare professionals owe these duties to all other people, whether they are patients or not, and quite independent of our professional qualifications.

- 4.6.2 As qualified and licensed professionals they have "moral obligations", for example, to provide healthcare, relieve pain, gain informed consent, respect confidentiality, and to be truthful.
- 4.6.3 Institutional duties: Institutional duties are specific to the healthcare practitioner's particular institutionalised role, for example the duties of a practitioner employed by a company, a healthcare practitioner working in a governmental research agency, or a healthcare practitioner engaged in private practice. These duties are contained in employment contracts, job descriptions etc. Institutional duties must however also be consistent with the ethical and legal duties of healthcare practitioners.
- 4.6.4 Legal duties: Legal duties are imposed by the common law and by statutes (for example, the National Health Act No. 61 of 2003 or the Health Professions Act No. 56 of 1974) that require healthcare practitioners to follow certain procedures and to use particular skills 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 healthcare practitioner as a professional.
- 4.8 No duty is absolute or can be held without exception irrespective of time, place, or circumstance. This is not surprising, since different duties may prescribe opposite decisions and actions in specific or real-life situations. For example, practitioners' duties to patients may compete with employers' expectations. Or the duty to respect a patient's confidentiality may clash with the duty to protect innocent third parties from harm. These are instances of conflicts of interest or dual loyalties.
- 4.9 The catalogue of general duties below, presents a fairly comprehensive picture of what it is that binds healthcare providers as professionals to their patients, as well as to others. They also are the basis on which, if these duties are not honoured without justification, that the HPCSA may impose sanctions on health professionals.
- 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 broad guide but informed by 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 PATIENT'S BEST INTERESTS OR WELL-BEING

Health care practitioners must:

- 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' healthcare. Beliefs that might prejudice care include a patient's race, culture, ethnicity, social status, lifestyle, economic worth, age, gender, disability, disease status, sexual orientation, religious or spiritual beliefs, and any other perceived or real condition of vulnerability.
- 5.1.6 If they feel that their personal beliefs might affect the treatment they provide, they must explain this to their patients, and inform them of their right to seek care from other healthcare practitioners.
- 5.1.7 Not refuse or delay treatment because they believe that patients' actions have contributed to their condition, or because they the healthcare practitioners may be putting their own health at risk.
- 5.1.8 Apply their mind openly 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, healthcare provider in community service, or healthcare practitioner who is not appropriately registered with the HPCSA, as locum tenens or otherwise in their own or any associated healthcare 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 as potentially creating a conflict of interest or dual loyalty in respect of their care of that patient.
- 5.1.13 In emergency situations, provide healthcare within the limits of their practice and according to 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.
- 5.1.14 Provide emergency interventions when required:

In an emergency, where there is threat to life or limb (including a perceived threat) and where no appropriately trained healthcare professional is available, then the practitioner must intervene to the best of their ability.

5.1.15 Be appropriately educated and trained:

To qualify as appropriately educated and trained, the individual practitioner must have successfully completed a training programme approved and accredited by the relevant Board for registration purposes with the following requirements also met:

- a) The training entity/institution/hospital needs to be accredited by the board for training in that particular profession or discipline and for that particular competency.
- b) The trainee must have completed a duration of under and/or postgraduate training as laid down by the Board.

- c) The trainee must have been evaluated and certified as having met the requirements of the training programme by an entity accredited by the Board (e.g. Colleges of Medicine, Universities).
- d) Short courses can only be recognised as enhancing or maintaining skills within the field of practice and category of registration in which the practitioner had already been credentialed and registered by the Board.
- e) Practice should be within the scope of the practitioner's profession as laid down by the Board and is judged by the standards and norms considered reasonable for the circumstances under which the intervention took place.
- 5.1.16 Be sufficiently experienced:
- a) Initial training under supervision as defined in clause 5.1.15 (b) above, by an entity accredited by the Board for such purposes.
- b) Certification of successful completion of such training.
- c) With any intervention, proficiency must be demonstrable, taking into account and judged by the standards and norms considered reasonable for the circumstances under which the intervention took place.
- d) The introduction of new interventions within the practitioners' scope of profession is only permissible if the practitioner has undergone further appropriate training as approved by the Board.
- 5.1.17 Work under proper conditions and surroundings:

All interventions must take place under appropriate conditions and surroundings. These are subject to judgement by the Board as to what is considered reasonable for the circumstances, surroundings and conditions, under which the intervention took place. No practitioner may embark upon an intervention unless he/she feels that it is in the patient's interest, and other than in a life or limb threatening emergency, that it is safe to do so. The practitioner will be judged on what requirements are reasonably needed to best ensure a patient's dignity, integrity and safety.

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5.2RESPECT FOR PATIENTS

Healthcare practitioners must:

- 5.2.1 Respect the privacy, confidentiality and dignity of patients.
- 5.2.2 Treat patients politely and with consideration (respect).
- 5.2.3 Listen to their patients and respect their opinions.
- 5.2.4 Not engage in improper relationships with their patients/clients and those who may be accompanying the patient.
- 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 examination.
- 5.2.7 Inform the patient if the practitioner will be having a chaperone in the room during an intimate examination.

5.3INFORMED CONSENT

Healthcare practitioners must:

- 5.3.1 Always seek informed consent from patients ahead of providing any treatment or care, including taking of history and examination
- 5.3.2 Fully inform their patients about their condition, its treatment and prognosis.
- 5.3.3 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.
- 5.3.4 Refrain from withholding from their patients any information, investigation, treatment, or procedure that the healthcare practitioner knows would be in the patient's best interests.
- 5.3.5 Apply the principle that informed consent is an on-going, iterative process.
- 5.3.6 Allow patients access to their medical records.

[For detailed information consult the HPCSA Ethical Booklet 4 on Informed Consent]

5.4 PATIENT CONFIDENTIALITY

Healthcare practitioners should:

- 5.4.1 Recognise the right of patients to be upheld by the healthcare practitioners to not disclose any personal and confidential information they acquire in the course of their professional duties, unless the disclosure thereof is:
- 5.4.1.1 made in accordance with the express patient's informed consent;

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- 5.4.4.2 made in accordance with a court order to that effect; required by law; or
- 5.4.1.3 In the interest of the patient (See sections 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 HEALTHCARE

Healthcare 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 refuse 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

Healthcare 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

Healthcare practitioners should:

5.7.1 Promote access to healthcare. If they are unable to provide a service, they should refer the patient to another healthcare practitioner or to a healthcare 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.

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5.8

ALLOCATION OF CRITICAL SCARCE HEALTHCARE RESOURCES: ETHICAL CONSIDERATIONS

The following principles should be considered when deciding allocation of scarce healthcare resources. The process to allocate the resources shall be transparent, inclusive, accountable, and consistent throughout the period:

- 5.8.1. Fairness: Each person's interest should count equally, irrespective of race, ethnicity, creed or gender.
- 5.8.2 Equity: Allocation of resources shall be impartial regardless of patient's social circumstances and ability. Notwithstanding, resources allocation should prioritise those in society with the greatest need.
- 5.8.3 Application: It is most appropriate to guide the allocation of scarce resources among individuals or populations who can be expected to derive the same benefit from the resource, for example, vaccines among high-risk populations, or ventilators among those with similar clinical indicators for benefit.

- 5.8.4 Best outcome: This principle can be used to justify the allocation of resources according to their capacity to do the best or minimize the most harm, for example, using available resources to save the most lives possible. May be most appropriate to guide the allocation of scarce resources that confer substantially different benefits to different individuals, for example, ventilators to those expected to derive the most benefit.
- 5.8.5 Prioritise the worst off: This principle can be used to justify the allocation of resources to those in greatest medical need or those most at risk. May be most appropriate to guide the allocation of resources that are designed or intended to protect those at risk, for example, PPE for healthcare workers, vaccines for those most at risk of infection and severe illness, or those most in need, as in the case of provision of drugs in short supply to those needing them most urgently.
- 5.8.6 Prioritise those tasked with helping others: This principle can be used to justify the allocation of resources to those who have certain skills or talents that can save many other people, or because something is owed to them on account of their participation in helping others. Most appropriate to guide the allocation of resources to healthcare workers, first responder etc.

5.9 POTENTIAL CONFLICTS OF INTEREST

Healthcare practitioners should:

- 5.9.1 Always seek to give priority to the investigation and treatment of patients solely based on clinical need.
- 5.9.2 Avoid over-servicing and only recommend or refer patients for necessary investigations and treatment, and should only prescribe treatment, drugs or appliances that serve the needs of their patients.
- 5.9.3 Declare to their patients verbally and by a displayed notice any pecuniary interest they have in institutions, diagnostic equipment, or the like to which they make referrals.

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- 5.9.4 Refrain from coercing patients or their family members.
- 6. DUTIES TO COLLEAGUES AND OTHER HEALTHCARE PRACTITIONERS
- 6.1 REFERRALS TO COLLEAGUES AND POTENTIAL CONFLICTS OF INTEREST

Healthcare 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 inducement or incentive, from colleagues to whom they refer patients as it may affect or be seen to affect the healthcare practitioners' 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.]

6.2 WORKING WITH COLLEAGUES

Healthcare practitioners should:

- 6.2.1 Work with and respect other health- professionals in pursuit of the best healthcare possible for all patients.
- 6.2.2 Not discriminate against colleagues, including but not limited to healthcare 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 healthcare practitioners (See Rule 12 of the ethical Rules of conduct).

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- 6.2.4 Not make a patient doubt the knowledge or skills of colleagues by making comments about them that cannot be 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 or report them to the HPCSA for assistance.

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7. DUTIES TO PATIENTS OF OTHER HEALTH CARE PRACTITIONERS

Healthcare practitioners must:

- 7.1 Act expediently 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

Healthcare practitioners must:

8.1.1 Maintain and improve the standard of their performance by keeping their

professional knowledge and skills, including their knowledge and skills related to ethics, human rights and health law, 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.

- 8.1.2 Acknowledge the limits of their professional knowledge and competence.
- 8.1.3 Observe and keep up to date with the laws that affect professional healthcare practice in general and their practice, in particular (for example, the provisions of the National Health Act No. 61 of 2003).
- 8.1.4 For detailed information, consult the HPCSA guidelines for Continuing Professional Development.
- 8.2 MAINTAINING A PROFESSIONAL PRACTICE

Healthcare practitioners should:

- 8.2.1 Keep their equipments and analysers in good working order.
- 8.2.2 Maintain proper hygiene in their working environment.
- 8.2.3 Keep accurate, detailed 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

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- 9. DUTIES TO SOCIETY
- 9.1 ACCESS TO SCARCE RESOURCES

Healthcare practitioners should:

- 9.1.1 Deal responsibly with scarce healthcare 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 HEALTHCARE POLICY DEVELOPMENT
- 9.1.2. Healthcare practitioners should include, amongst other health-related and clinical foci, ethical considerations, legal requirements and human rights in the development of healthcare policies.
- 10. DUTIES TO THE HEALTH CARE PROFESSION
- 10.1 REPORTING MISCONDUCT

Healthcare practitioners must:

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.

11. DUTIES TO THE ENVIRONMENT

11.1 CONSERVATION OF NATURAL RESOURCES

Healthcare 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 HEALTHCARE WASTE

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

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Ethical guidelines for good practice in the healthcare professions

THE HEALTHCARE PROFESSIONS COUNCIL OF SOUTH AFRICA

GUIDELINES FOR GOOD PRACTICE

IN THE HEALTHCARE PROFESSIONS

SEEKING PATIENTS' INFORMED CONSENT:

THE ETHICAL CONSIDERATIONS

BOOKLET 4

REVISED: DECEMBER 2021

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THE SPIRIT OF PROFESSIONAL GUIDELINES

Good clinical practice is based on a trust relationship between patients and healthcare professionals. Being a good healthcare practitioner requires a life-long commitment to sound professional and ethical practice and an overriding dedication to the interests and wellbeing of one's fellow human beings and society. This makes the practice in the healthcare profession a moral enterprise. It is in this spirit that the HPCSA presents the following ethical guidelines to guide and direct practice by healthcare practitioners. These guidelines are an integral part of the standards of professional conduct against which professional conduct is evaluated.

[Note: The terms "healthcare practitioner" and "healthcare professional" in these guidelines refer to persons registered with the HPCSA].

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1. GUIDANCE TO HEALTHCARE PRACTITIONERS

Being registered under the Health Professions Act No. 56 of 1974 (as amended) gives healthcare practitioners certain authority and privileges. In return, practitioners must meet the standards of competence, care and conduct set by the Health Professions Council of South Africa (HPCSA).

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

2. INTRODUCTION

- 2.1 Successful professional relationships between healthcare practitioner and patients depend upon mutual trust. To establish that trust, practitioner must respect patient's 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. Patient must be given sufficient information in a manner 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's ethical rules and guidelines. Healthcare practitioner is expected to be aware of the laws in this regard. The laws prescribe the minimum requirements when seeking informed consent from patient.
- 2.3 Effective communication is key to enabling patients to make informed decisions. Healthcare practitioner must take appropriate steps to ensure that patient is provided with information about their condition and its treatment. Such dialogue with patient leads to clarity of objectives and understanding and strengthens the quality of the relationship between healthcare practitioner and patient. It provides an agreed framework within which healthcare practitioner can respond effectively to the individual needs of patient. Patient who makes properly informed decisions about their healthcare is 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 Patient is entitled to information about his/her 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, patient 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 Patient has 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 patient want or ought to know, before deciding whether to consent to treatment or an investigation, include:
- 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 practitioner 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 (patients should be informed of their right to refuse the involvement of students);
- 3.1.3.10 A reminder that patient can change his/her mind about a decision at any time;
- 3.1.3.11 A reminder that patient 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, healthcare practitioner 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. Healthcare practitioner should not make assumptions about patients' views but should discuss these matters with them and ask them whether they have any concerns

about the treatment or the risks it may involve. Healthcare practitioner should provide patient with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Patient should be asked whether they have understood the information and whether they would like more before making a decision.

- 3.1.5 Healthcare practitioner must not exceed the scope of the authority given by a patient, except in an emergency. Therefore, healthcare practitioner 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 healthcare practitioners provide particular elements of an investigation or treatment (for example anaesthesia during surgery) and where such situation arise, it is incumbent for each practitioner to engage the patient separately and fully for the consent to be completely informed;
- 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, healthcare practitioner 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 consent 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 Healthcare practitioner should raise with patient 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. Healthcare practitioner must abide by patients' decisions on these issues. If in exceptional circumstances healthcare 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. Healthcare practitioner 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. Healthcare practitioner 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

Healthcare practitioner 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 practitioner providing the care. In any given situation where there's limitation in their competence/experience to provide the fullest possible answer, they should commit to seek the additional information from credible sources and provide same to the patient. Healthcare practitioner must answer such questions as fully, accurately and objectively as possible.

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3.3 WITHHOLDING INFORMATION

- 3.3.1 Healthcare practitioner should not withhold information necessary for decision making, unless they judge that disclosure of some information could 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 healthcare 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 healthcare practitioner to withhold information and make decisions on their behalf or nominate a relative or third party to make decisions for them, the healthcare practitioner should explain the importance of patient knowing the options open to them, and what the treatment they may receive will involve. If patient insist that they do not want to know in detail about their condition and its treatment, the healthcare practitioner should still provide basic information about the treatment. If a relative asks a healthcare practitioner to withhold information, the latter must seek the views of the patient. Again, healthcare practitioner should not withhold relevant information unless they consider that it would cause the patient serious harm.

- 3.3.4 The National Health Act provides that healthcare practitioner must provide patient 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 healthcare practitioner withholds relevant information from the patient, they must record this, and the reason for doing so, in the patient's health 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 healthcare practitioner and their patient or their next of kin which keeps them abreast of changes in the condition of patients and the treatment or investigation the practitioners propose. Whenever possible, healthcare practitioner 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 patient understand, healthcare practitioner should give clear explanations and give the patient time to ask questions. In particular, healthcare practitioner 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;

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- 3.4.2.3 Where appropriate, discuss with patients the possibility of being accompanied by a relative or friend, as appointed by patient;
- 3.4.2.4 Explain the probabilities of success, prognosis, 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 support groups, where appropriate;
- 3.4.2.6 Allow patient 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 healthcare 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 Obtaining of informed consent belongs exclusively with the primary practitioner and should not be delegated.

- 3.4.2.9 Ensure that, where treatment is not to start until sometime after informed consent has been obtained, patients are given clear instructions on how to review their decision with the healthcare practitioner providing the treatment.
- 3.4.2.10 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 healthcare practitioner providing treatment or undertaking an investigation has the responsibility to discuss it with the patient and obtain informed 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, healthcare practitioner 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 healthcare 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.

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5. THE RIGHT OF PATIENTS TO INFORMATION

- 5.1 Patients have a right to information about the healthcare services available to them, presented in a way that is easy to follow and use.
- 5.2 The National Health Act provides that healthcare providers (this includes healthcare 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 healthcare 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

patient, but they must not put pressure on patient to accept their advice. In discussions with patients, healthcare practitioners should:

- 6.1.1 Give a balanced view of the options;
- 6.1.2 Explain the need for informed consent.
- 6.2 Healthcare practitioner 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. Healthcare practitioner should do their best to ensure that patient has considered the options and reached their own decision. Healthcare practitioner should take appropriate action if they believe patient is 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, healthcare 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, healthcare practitioner 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, healthcare practitioner must respect the terms of any valid advance refusal by the patient which they know about, or which is drawn to their attention.

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- 7.3 After the emergency healthcare practitioner 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 Healthcare practitioner 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 healthcare 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 healthcare practitioner 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. 35 of 2005) or the Choice on Termination of Pregnancy Act (Act No.92 of 1996), health care practitioners should make sure that the children have sufficiently mental maturity 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 patient has difficulty retaining information or are only intermittently competent to make a decision, healthcare practitioner should provide any assistance they might need to reach an informed decision.
- 8.2.2 Healthcare practitioner should record any decision made while the patient was competent, including the key elements of the consultation.
- 8.2.3 Healthcare practitioner should review any decision made whilst the patient was 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 Healthcare practitioners should also consult the provisions of the Mental Health Care Act (Act No.17 of 2002) when dealing with mentally ill patients.

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8.4 THIRD PARTY NOMINATIONS IN REGARD TO CONSENT

- 8.4.1 The National Health Act allows patient while still mentally competent to mandate another person in writing to give consent on their behalf
- 8.4.2 If healthcare practitioner is 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 disabilities, 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 Healthcare practitioner 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 Healthcare practitioner 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 risks and consequences of non-treatment.
- 8.5.3 A healthcare 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)).

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- 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 a 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, healthcare practitioner 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 healthcare team's knowledge of the patient's background, such as cultural, religious or employment considerations;

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- 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, or third party is not nominated, healthcare practitioner 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 Healthcare practitioner should seek the court where a patient lacks capacity to consent to a medical intervention and the situation is contentious for example, parent withholding consent to life-saving treatment for children under the age of 12 years, in other words, in any situation where the interest of the patient is protected by a constitutional right.
- 10.3 Where healthcare practitioner decides 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, healthcare 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 recorded 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 healthcare 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, healthcare 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;

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- 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 Healthcare practitioner must use the patient's formal health records 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 deceased people (National Health Act, 2003). Healthcare practitioners need to consult the law in this regard when carrying out such procedures.

14. IMPLIED CONSENT

Healthcare practitioner 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. Healthcare 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.

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- 16.2 Healthcare practitioner 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. Healthcare practitioner must pay particular attention to ensuring that the information the person wants or ought to have is identified and provided. Practitioner 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

Healthcare provider 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's consent to release ICD-10 coding to the medical scheme and/or (where required) to the other health professional (within the healthcare 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

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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 patient by the provider 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.

Provider 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 HEALTHCARE TEAM

Sharing of information with members of a healthcare 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.

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Ethical guidelines for good practice in the health care professions

HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

GENERAL ETHICAL GUIDELINES FOR

GOOD PRACTICE IN TELEHEALTH

Booklet No: 10

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THE SPIRIT OF PROFESSIONAL GUIDELINES

Good clinical practice is based on a trust relationship between patients and health care professionals. Being a good health care practitioner, requires a life-long commitment to sound professional and ethical practice and an overriding dedication to the interests and wellbeing of one's fellow human beings and society. This makes the practice in the health care profession a moral enterprise. It is in this spirit, that the HPCSA presents the following ethical guidelines to guide and direct the practice of health care

practitioners. These guidelines are an integral part of the standards of professional conduct against which professional conduct is evaluated.

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

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DEFINITIONS

Telehealth is the application of electronic telecommunications, information technology or other electronic means to administer healthcare services in two geographically separated locations for the purpose of facilitating, improving, and enhancing clinical, educational and research, particularly to the under serviced areas in the Republic of South Africa. Telehealth is a blanket term that covers all components and activities of healthcare and the healthcare system that are conducted through telecommunications technology.

"Social media" means the online tools and any electronic platforms that people use to share content such as opinions, information, photos, videos, and audio. Social media includes social networks (e.g., Facebook, Twitter, WhatsApp, Tik Tok 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 or other similar platforms.

"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

"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.

"Practitioner in charge" 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.

"Consulting practitioner" refers to the practitioner who offers advice or intervention or patient information from a remote location.

"Patient" is the patient who consents to be treated by the registered practitioner. "Healthcare" means the maintenance or improvement of health via the prevention, diagnosis, treatment, recovery, or cure of disease, illness, injury, and other physical and mental impairments in people.

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"Triage" means sorting of and allocation of treatment to patients according to a system of priorities designed to maximize the number of survivors, taking into account survival, quality of life using available resources.

"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.

"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.

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1. INTRODUCTION

- 1.1 Health Professions Council of South Africa (HPCSA) is mandated to regulate healthcare provision by ensuring that healthcare services are provided by qualified, skilled, and competent healthcare practitioners. This regulatory mandate applies to healthcare practitioner in both state and private health care institutions. The HPCSA protect the public against possible abuse by healthcare practitioner on one hand and to provide guidelines for good practice to the professions.
- 1.2 Previously, the HPCSA's referred to these guidelines as "Telemedicine". However, it has been resolved that a more inclusive term to accommodate all relevant professions, namely, Telehealth, be used going forward. Telehealth can contribute to achieving universal health coverage by improving access for patients to quality, cost-effective, health services wherever they may be. It is particularly valuable for those in remote areas, vulnerable groups, and ageing populations.
- 1.3 The objective of Telehealth system is to deliver healthcare services at a distance, especially to South Africans residing in under-served areas. The system was established to alleviate the human resource crisis as experienced and is geared to improve the links and communication between developed and undeveloped healthcare facilities and different categories of healthcare practitioners.
- 1.4 These guidelines are intended to guide practitioners who use Telehealth to always ensure that, the clinical needs of patients are met with favourable outcomes to the benefit of the patient.
- 1.5 The 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:
- i. Booklet No 1: General ethical guidelines for healthcare professions
- ii. Booklet 4: Patient consent
- iii. Booklet No 5: Confidentiality
- iv. Booklet No 9: Keeping of patient records

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2. PURPOSE

The purpose of these guidelines is to:

- 2.1 provide an ethical framework that draws from the core values and standards;
- 2.2 to provide guidance to practitioners engaged in Telehealth practices in South Africa.

3. APPLICABILITY OF TELEHEALTH

- 3.1 Telehealth involves secure videoconferencing or similar forms of technology which enable healthcare practitioners to replicate, as far as practical, the interaction of traditional face-to-face consultations between healthcare practitioners and patients. In this regard, information is exchanged electronically either s synchronous or asynchronous (that is on or off-line) formally, informally or as a need for support by from consulting practitioner remotely.
- 3.2 Any suitable Information and Communication Technology (ICT) platforms, such as cellular phones, telephone, Skype, Teams, Goole meet or any similar virtual technology, to exchange information for the diagnosis and treatment of diseases and injuries, research, and evaluation, and for the continuing education of health professionals. Although Telehealth 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 that practitioners must carefully consider.
- 3.3 When using Telehealth, all principles of good practice in relation to patient consent, confidentiality, and good record keeping etcetera still apply.
- 3.4 The usage of social media platforms for the purpose of Telehealth is not desirable. 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 ethical dilemmas.

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- 3.5 The Protection of Personal Information Act (POPIA) outlaws the acquisition of data about an individual's personal, including health, outside a healthcare setting. 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.
- 3.6 Health practitioners may choose to share personal information about themselves with their patients during face-to-face consultations, and social media does not offer a similar level of control over the extent of dissemination and type of content shared.
- 3.7 Telehealth is intended to be utilised to replicate physical consultations as far as possible, but not as a substitute. It is desirable that the practitioner shall have established professional relationship with their patient before Telehealth services can be considered, although, this is not a compulsory requirement, depending on existing conditions.
- 3.8 No practitioner may exclusively render professional services through Telehealth.

4. TYPES OF TELEHEALTH

- 4.1 Routine Telehealth
- a) Commonly patient-initiated or used by practitioner to obtain second opinion from other practitioners. Should preferably be practised in circumstances where there is an already established practitioner-

patient relationship, and where such a relationship does not exist, practitioners may still consult using Telehealth provided such consultations are done in the best clinical interest of patients.

b) This practice 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.

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4.2 Specialist Telehealth

- a) Specialist Telehealth consultations form the bulk of Telehealth 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-serviced.
- 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.
- 4.3 Emergency Telehealth
- a) Emergency Telehealth involves judgements by the healthcare practitioner often based on sub-optimal patient information.
- b) In emergencies, the health and wellbeing of the patient is the determining factor with regard to stabilising the patient and having the patient referred for thorough medical care.
- c) The practitioner must provide acute treatment and refer to emergency facility, if necessary for further treatment of the patient.
- d) The emergency instructions should be in writing and appropriate to the services being rendered via Telehealth platforms.
- 5. ETHICAL GUIDELINES
- 5.1 Competence, Registration and Authorisation
- a) According to the Health Professions Act no 56 of 1974 (as amended), 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 scope which has been defined by the Minister in terms of the Act.
- b) Only practitioners who have been deemed competent and are registered in their respective professions are authorised to participate in Telehealth practice in South

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

c) In the case of Telehealth across country's borders, practitioner serving South African patients should be registered with the regulating bodies in their original states as well as with the HPCSA.

- d) Practitioners (in charge of patient and consulting) are held to the same standards of professional practice as healthcare practitioners who conduct face-to-face consultations. Practitioners collaborating in Telehealth are required to ensure that each they are both registered with HPCSA, before embarking on the clinical consultation.
- e) Practitioners in charge of the patient shall be duly registered as independent practitioners.
- f) The servicing practitioner communicates the information to the patient at remote location and may also contact other practitioners to provide the necessary assistance, if required.
- g) The practitioner in charge of the patient ensure that the triage process is conducted when consulting using Telehealth services.
- 5.2 Healthcare practitioner-patient relationship
- a) The relationship between the patient and the healthcare practitioner is established when the practitioner agrees to treat the patient and the patient provides informed consent to be treated.
- b) The relationship between the patient and the healthcare practitioner must be based on mutual trust and respect.
- c) Core ethical values as outlined in the HPCSA guidelines for healthcare practitioners are always applicable in Telehealth and the fact that a patient's personal information can be stored, processed, and moved using electronic means does not alter the ethical duties of health care practitioner in this regard.
- d) The professional discretion of healthcare practitioners engaging in Telehealth regarding the diagnosis, scope of care or treatment should not be limited or influenced by nonclinical considerations of Telehealth technologies.

- 5.3 Assumption of primary responsibility
- a) The practitioner in charge is 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.
- b) The consulting practitioner must also securely keep detailed records, online or otherwise, of the professional services he or she delivers as well as the information he or she receives and on which the advice is based.
- c) The consulting practitioner must further ensure that the advice on treatment given are understood by the consulting practitioner and/or the patient.
- d) Practitioner may charge consultations fees for services undertaken through Telehealth platforms.
- e) HPCSA strongly cautions against practices that may amount to over-servicing and perverse incentives.
- 5.4 Considerations for Telehealth

The decision to offer a remote consultation, other than in emergency, as opposed to a face-to-face consultation, should always take into account the following: -

- a) The need for review or to assess the severity of symptoms both physical and psychological,
- b) Previous knowledge of the patient/client as well as the family and wider situation, as appropriate, alongside access to their clinical records.
- c) A need to physically examine the patient/client.
- d) Previous medical history which may trigger a need to see the patient face-to-face.

It is good practice for practitioners to consider the social circumstances of the patient where the clinical or social background would require seeing the patient/client.

- 5.5 Evaluation and treatment of patients
- a) A documented medical evaluation must be done and the relevant clinical history necessary to diagnose underlying conditions as well as any contra-indications

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regarding the recommended treatment must be obtained before providing treatment, including issuing prescriptions, electronically or otherwise.

- b) Treatment, including issuing a prescription, based solely on an online questionnaire, does not constitute an acceptable standard of care.
- c) When prescribing care using Telehealth practitioners should ensure that express informed consent in accordance with the standards practice used in face-to-face issuing of prescriptions.
- 5.6 Professional duties
- a) Healthcare practitioners engaging in Telehealth must observe the professional duties outlined in the HPCSA's ethical guidelines for good practice.
- b) 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 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.
- c) Healthcare practitioner should not give medical advice or provide treatment using Telehealth without obtaining proper informed consent, orally recorded, or written, from the patient for both the treatment to be given and the use of Telehealth technology.
- d) The servicing healthcare practitioner should verify:
- i) The location of the consulting healthcare practitioner;
- ii) The identity and qualifications of the consulting healthcare practitioner;
- iii) The identity of the patient; and
- iv) The location of the patient
- 5.7 Duty to inform and informed consent

This section must be read in conjunction with HPCSA's guidelines regarding informed consent in Booklet 4 and the provisions of the National Health Act.

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- a) Informed consent for the use of Telehealth can be obtained in writing or recorded orally.
- b) Informed consent documentation for Telehealth practice should include the following:
- i) The identities of the patient and the servicing healthcare practitioner.
- ii) Agreement by the patient that the practitioner to decide whether the condition being diagnosed or treated is appropriate for a Telehealth consultation and if there is no consensus, the servicing practitioner in charge must ensure that face to face consultation is conducted.
- iii) The healthcare practitioner's practice number.
- iv) The types of transmissions consented to using Telehealth technologies (e.g., prescriptions, refills, appointment scheduling, patient education etc.).
- v) Details of the security measures taken with the use of Telehealth technologies, such as encrypting data, password protected screen savers and data files, or the use of other reliable authentication techniques.
- vi) Any material risks to confidentiality arising from the use of Telehealth technologies that may influence the patient's decision to consent.
- vii) The secure storing of the recordings of the consultations should be included in the statement.
- viii)The encryption of the stored information should also be included in the statement.
- ix) The patient's express consent to the transmission of the patient's personal medical information to a healthcare practitioner or other appropriate third parties.
- c) When Telehealth is used the patient should be informed regarding who will access their information, the purpose of the Telehealth service, the cost of the service and what the implications of the use of such information will be.
- d) It is the duty and responsibility of the practitioner in charge to obtain express informed consent for Telehealth purposes.

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- e) A copy of the consent form should be kept with patient's records and a duplicate given to the patient, when required.
- f) 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.
- 5.8 Patient confidentiality

- a) The patient must always be assured that their confidentiality is protected during Telehealth consultation.
- b) Patient confidentiality should be ensured at both the practitioners involved 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 5, which generally state that it is every practitioner's duty to make sure that information is effectively protected against improper disclosure at all times.
- c) HPCSA's guidelines 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.
- d) Policies and procedures for documentation, maintenance, and transmission of records regarding Telehealth consultations should be maintained at the same standard of care as face-to-face consultations.
- e) Policies and procedures for Telehealth should deal with:
- i) Confidentiality;
- ii) Healthcare personnel apart from the healthcare practitioners who will process the electronic information;
- iii) Hours of operation;
- iv) Types of transactions that are permitted electronically;

- v) Required patient information to be included in electronic communications (e.g., name, identification number and type of transaction);
- vi) Archival and retrieval oversight mechanisms; and
- vii) Quality oversight mechanisms.
- f) 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.
- g) 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.
- 5.9 Quality, security and safety of patient information and records
- 5.9.1 Quality
- a) Every registered healthcare practitioner engaging in Telehealth practices takes responsibility for the quality of service delivered as well as confidentiality, security, and safety of patients' information.

- b) Patient information and records should consist of copies of all patient-related electronic communications, including:
- i) Patient-practitioners communications;
- ii) Prescriptions;
- iii) Laboratory and test results;
- iv) Evaluations and consultations;
- v) Records of past care;
- vi) Instructions obtained or produced in connection to Telehealth technologies; and
- vii) Records of informed consents to treatment and use of Telehealth

The patient's health records, data and platform bandwidth, established during the session of Telehealth must be accessible, online, or physical, and documented for both the healthcare practitioners involved and their patients.

- c) The practitioner must ensure that the confidentiality mechanisms employed to ensure confidentiality must be available when required.
- d) 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.
- 5.9.2 Quality assurance
- a) Healthcare practitioners should not practice Telehealth 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 practitioners to ensure quality and integrity of the platform to maintain

confidentiality and that there is no critical loss of image resolution from acquisition to final display.

5.9.3 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.
- d) 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.
- e) All personal computers of the Telehealth service should be accessed by authorised personnel only through the use of a login password.
- f) 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?
- g) Access to information by other healthcare practitioners, patients or third parties 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.

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5.9.4 Safety

Health care practitioners using Telehealth shall: -

- 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
- d) HPCSA's guidelines on the keeping of patients' records in Booklet 9;
- e) Comply with the legal requirements for data messages in the Electronic Communications and Transactions Act No 25 of 2002, Protection of Personal Information Act No 4 of 2013 (POPIA) regarding the protection of personal information and the principles regarding the electronic collection of personal information.
- 6. PROTECTION OF PERSONAL INFORMATION Act No 4 of 2013 (POPIA)
- 6.1 Practitioners are advised to ensure that they manage patients' information in accordance with requirements of POPIA.

- 6.2 Practitioners must ensure that: -
- a) adequate safety of patient's personal information and processing by public and private bodies;
- b) the entity or practices establish minimum requirements for the processing of personal information;
- c) provide for the code of conduct for the management of patient data;
- d) they are always cognisant of rights of persons regarding unsolicited electronic communications and automated decision making protocols;
- e) ensure that the policy which regulates the flow of personal information generated from Telehealth is compliant to the Act requirements; for more information, see: https://popia.co.za/act/

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LIST OF ETHICAL GUIDELINES FOR GOOD PRACTICE IN THE HEALTH CARE PROFESSIONS

Booklet 1: General ethical guidelines for healthcare professions

Booklet 2: Ethical and professional rules of the Health Professions Council of South Africa as promulgated in government gazette R717/2006

Booklet 3: National Patients' Rights Charter

Booklet 4: Seeking patients' informed consent: The ethical considerations

Booklet 5: Confidentiality: Protecting and providing information

Booklet 6: Guidelines for the management of patients with HIV infection or AIDS

Booklet 7: Guidelines withholding and withdrawing treatment

Booklet 8: Guidelines on Reproductive Health management

Booklet 9: Guidelines on Patient Records

Booklet 10: Guidelines for the practice of Telehealth

Booklet 11: Guidelines on over servicing, perverse incentives and related matters

Booklet 12: Guidelines for the management of healthcare waste

Booklet 13: General ethical guidelines for health researchers

Booklet 14: Ethical Guidelines for Biotechnology Research in South Africa

Booklet 15: Research, development and the use of the chemical, biological and nuclear weapons

Booklet 16: Ethical Guidelines on social media

Booklet 17: Ethical Guidelines on Palliative Care