SAMED CODE OF BUSINESS PRACTICE

Updated and approved by the SAMED Board

Date: 8 December 2011

Message from the Board of Directors at SAMED

The healthcare industry is one of the most carefully scrutinized industries in the world. This Code of Business Practice contains valuable information about the many laws, codes, and procedures that govern the way we do business in South Africa, and in particular, how we conduct interactions with Health Care Professionals (HCPs). It helps to further define our commitment as an industry and as individuals to abide by government laws, industry standards and procedures that apply to our day-to-day interactions.

As a member of SAMED, you are bound by this code. You must read this code and should you become aware of a violation of this code, you must report it through the appropriate channel. Note, failure to report a violation is itself a violation.

From the outset, it is important to emphasize that the Code underpins SAMED's vision i.e.:

To develop a sustainable medical device industry by responsibly improving patient access to innovative health technology.

Purpose of the Code:

The fundamental purpose of the Code is to promote and encourage among SAMED Members, ethical principles and practices. As such it is envisaged that the Code will become an essential guide and support for SAMED Members in their business interactions with their customers. The Code is not a rule book, but gives guidance, and this guidance springs from chosen ethical values. Such ethical values include:

a. an industry that is socially responsible towards not only its customers, but to society at large and patients in particular and

b. the desire to promote a spirit of co-operation and shared responsibility among public and private HCPs and providers, which shall include the State, as well as other relevant sectors, within the context of effective, efficient and transparent health care delivery.

In support of these values, the underpinning principle of the Code is that SAMED Members will not offer any inappropriate inducement to an HCP or other customer in order to sell, lease, recommend, or arrange for the sale or lease of their products.

SAMED will endeavour to ensure that the Code is circulated to all key Stakeholders i.e. HCPs, Hospitals, Government, Tender Authorities, Funders etc and that it be accepted as the basis for engagement with these parties.

The SAMED Code is binding on all SAMED Members and is a condition for new and ongoing Membership. The Code will be continuously reviewed (at least once per annum), borrowing from best practice both locally and globally. The Code also includes a set of Guidelines to assist SAMED Members in the interpretation and practical implementation of the Code.

Infringements of the Code will be dealt with through the efforts of a formally constituted 'SAMED Ethics Committee' governed by documented and legally compliant processes. SAMED urges its Members to adhere to the Code and report any infringements to the SAMED office using the procedures set out in Part B.

Disclaimer:

SAMED bears no responsibility for the conduct of any of its Members who may be alleged to be in contravention of this Code. SAMED also bears no responsibility for the non-enforcement of this Code.

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1. INTRODUCTION: GOAL AND SCOPE OF SAMED CODE OF BUSINESS PRACTICE

1.1 SAMED is committed to the following principles:

1.1.1 To ensure that all activities of SAMED shall be in the best interests of its Members, provided that such shall not detract from the needs and rights of patients;

1.1.2 To promote and encourage among its Members **ethical principles and practices**, voluntarily agreed upon, and to this end, to ensure that a Code of Business Practice which shall be binding on all Members, is published.

1.1.3 To the establishment of a healthcare system that is **people centred, equitable, coherent and efficient** and in particular to the contribution that high quality, cost-effective healthcare technology can make toward achieving good health outcomes.

1.1.4 To ensure **fair competition** between Members based on the value of products and associated marketing skills, and not based on any unacceptable business practice.

1.1.5 SAMED encourages ethical business practices in interactions between its Members and HCPs, in particular that Members will not offer any inappropriate inducement to an HCP or other customer in order to sell, lease, recommend, or arrange for the sale or lease of their products.

1.1.6 Thus, in pursuing this mission, SAMED Members ("Members") recognise, respect and encourage adherence to ethical standards and compliance with both the spirit and letter of applicable laws and guidelines in all business endeavours.

1.1.7 Members recognise that all South Africans have the right of access to healthcare, and that right should be progressively realised through co-operation and shared responsibility between the private and public healthcare sectors.

1.1.8 Members furthermore support an industry that is socially responsible towards not only its customers, but to society at large and patients in particular.

1.2 Interactions between Medical Device Industry and HCPs

There are many forms of interactions between the Medical Device Industry and HCPs. Such interactions act to advance medical science and improve patient care. This is a distinguishing feature of the Medical Device and IVD industries and such interactions act as a backdrop to the following:

1.2.1 Advancement of Medical Technology: The development of innovative medical devices and the improvement of existing products requires collaboration between Industry and HCPs.

Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the facilities of medical device companies.

1.2.2 Safe and Effective use of Medical Technology: The safe and effective use of medical technology requires that Industry offer HCPs appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval.

1.2.3 Research and Education: Industry's support of bona fide medical research, education, and enhancement of professional skills contributes to patient safety and increased access to new technology.

2. APPLICATION OF THE CODE

2.1 This Code and well as the SA Code of Practice for Marketing of Health Products binds Members of SAMED, whether such Members are manufacturers, importers, distributors or agents and includes their employees, agents and contractors working for or in conjunction with such Member, as well as marketing agencies, advertising agencies, event management entities, commission agents or independent sales representatives, procurement or software entities, working for or on behalf of a SAMED Member. Members should ensure that reference is made to these Codes in agreements with third parties mentioned in this context.

2.2 All Members are urged to adopt polices and procedures relating to this Code, which includes mechanisms to ensure that all events, sponsorships, marketing and advertising campaigns are signed off by a responsible senior staff member, which member has to take responsibility for all regulatory compliance, which includes compliance with this Code.

2.3 Members are under an obligation to workshop and communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code.

2.4 This Code is intended to facilitate ethical behaviour and is not intended to be, nor should it be construed as, legal advice.

3. INTERPRETATION AND DEFINITIONS

3.1 This Code does not substitute any obligation or provision found in any other Code dealing with the same or similar practices, including but not limited to the SA Code of Practice for Marketing of Health Products, and is intended to align with, amongst others the provisions of the Prevention and Combating of Corrupt Activities Act No 12 of 2004, the National Health Act No 61 of 2003, the Health Professions Act No 56 of 1974 as amended, the Medicines and Related Substances Amendment Act No. 72 of 2008 and its principal Act and all policies and guidelines issued in terms of the aforementioned legislation, the Competition Act No 89 of 1998 and all other relevant laws applicable to businesses and activities in the health sector.

Members may be simultaneously bound by these laws, as well as the Code.

3.2 In drafting the Code, regard has also been made to various international and local Codes currently binding the medical device industry, and interpretations awarded to such Codes may guide the interpretation of this Code.

3.3 Any interpretation of the provisions of this Code, as well as Members' interactions with HCPs not specifically addressed in this Code, should be made in light of the following principles:

3.3.1 **The Principle of Separation** (patient best interest): Interaction between industry and HCPs must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Members' products. Members may therefore not hold positions on any Executive Committee or Board of any Medical Association, Society or other healthcare organisation where a conflict of interest may occur.

3.3.2 **The Principle of Transparency**: Interaction between industry and HCPs must be transparent and comply with national and local laws, regulations and professional codes of conduct.

3.3.3 **The Principle of Equivalence**: Where HCPs are engaged by a Member to perform a service for or on behalf of a Member, the remuneration paid by the Member must be commensurate with, and represent a fair market value for, the services performed by the HCP.

3.3.4 **The Principle of Documentation**: For interactions between a Member and a HCP, such as where services are performed by an HCP for or on behalf of a Member, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Member. The activities envisaged by the agreement must be substantiated and evidenced by activity reports, financial records and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the Member to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

3.3.5 **Paci Principles:** Partnering against corruption initiative: An initiative of the World Economic Forum in partnership with Transparency International and the Basel Institute on Governance. See attachment.

3.4 In the context of this Code, and unless the particular context indicates otherwise, the following words and phrases carry the following meaning:

3.4.1 **"Company Code Compliance Officer"** means anyone duly authorised by the company, or appointed by the company in writing, to sign documents or give instructions on behalf of the company in relation to provisions in the code.

3.4.2 **"HCP"** includes Healthcare Professionals and Healthcare Facilities, and therefore includes individuals, entities, their employees or employers, their agents or other delegates, and includes, but is not limited to persons registered with the Health Professions Council of South Africa (HPCSA), Allied Health Professions Council, the Nursing Council, the Pharmacy Council, the Engineering Council for Clinical Engineers and includes institutions registered at the Department of Health or other regulatory or organisational body, such as a health facility (which includes hospitals, step-down facilities, etc), managed care companies, etc; which entities purchase, lease, recommend, use, maintain or arrange for the purchase or lease of, Members' medical technology products in South Africa.

3.4.3 **"Medical technology", "Medical devices", "Health Technology"** refers to medical devices as defined in the Medicines and Related Substances Amendment Act, 2008, and include in-vitro diagnostics.

3.4.4 **"Members"** means organisations that are Members of the South African Medical Device Industry Association ("SAMED") as defined in the SAMED Constitution, and includes their employees, agents and contractors working for or in conjunction with such Member.

3.4.5 **"Scientific meetings", "Advisory Boards", "Clinical Committees"** refers to meetings that are not necessarily conducted under the auspices of an independent scientific committee and which are not generally open to the whole scientific community affected, and includes meetings where pertinent clinical, healthcare or treatment issues are discussed which may relate to a particular issue (such as a treatment protocol for a particular disease), or which may be called by a Member in order to advise the Member on the impact or use of its specific technology, the clinical merits or place of the technology in treatment within a certain disease area, etc.

3.4.6 **Unacceptable fees"** refer to the payment of data, marketing, formulary, managed care or similar types of fees which are used to encourage or increase the purchase, loan or use of a medical device and which data, marketing or managed care is of no or limited value to the buyer or which services or information is not legitimately and actually provided by the seller, or which is not in existence; and which is bought solely, or mostly in order to reward or secure a particular purchase or utilisation behaviour, whether under implicit or explicit conditions relating to such behavioural change or sustained behavior.

PART A: BUSINESS AND FINANCIAL ARRANGEMENTS

4. LOAN OR PLACED EQUIPMENT

The sale or placement of equipment with a HCP, where the contract between the Member and the HCP includes the purchase of consumables / disposables associated with the equipment are subject to the following provisions:

4.1 HCPSA's Guidelines for Good Practice – Booklet 5, item 3.6 Technological Equipment as applicable to HCP's: **"3.6 TECHNOLOGICAL EQUIPMENT**
3.6.1 Health care practitioners shall only own and use technological equipment if it forms an integral part of their scope of the profession and practice and on condition that the health care practitioner concerned has received appropriate training in using and managing such equipment.
3.6.2 Health care practitioners shall not over-use equipment for procedures, tests and other applications that are not indicated, scientific or based on evidence. This constitutes overservicing and is prohibited.
3.6.3 Health care professionals shall not use technological equipment, health care products or devices for profiteering and must refrain from charging patients fees for the use of such products or devices that are not market related. "

4.2 The consumables are used to cross-merchandise the capital equipment in a manner which is defensible and fair.

4.2 The consumables relate to the specific piece of capital equipment being financed by means of the purchase of the consumables and is defensible in terms of, for example, the provisions of the National Credit Act.

4.5 The placement of equipment agreement should be in writing and, in cases of valid complaints, made available as per the complaints handling process in Part B: Dealing with Infringements of the Code.

5. BONUSING, REBATES AND INCENTIVE SCHEMES

5.1 Members ought to provide accurate, transparent and responsible billing information to HCPs, reimbursement authorities and other payors. Such documentation should be in writing and in cases of valid complaints should be available as per the complaints handling process in Part B:

5.2 Members are expected to follow the principles of acceptable invoicing procedures as detailed in the SAMED Policy on Transparent Invoicing. See Addendum 1.

5.3 No Member may offer a bonus, free goods or other incentive scheme deemed to be perverse, to an HCP in relation to the acquisition of goods and services in contravention of regulations to be issued in terms of section 18A and B of the Medicines and Related Substances Act, with particular reference to the Amendments as contained in Act 72 of 2008, notwithstanding that this law has not yet been implemented.

6. ROYALTY ARRANGEMENTS

6.1 HCPs, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve Medical Devices or Medical technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement.

6.2 A Member should enter into a royalty arrangement with an HCP only where the HCP is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

6.3 Arrangements involving the payment of royalties to an HCP must be formalised in a written agreement, which may be subject to scrutiny by the SAMED Ethics Committee if such interaction forms part of a complaint lodged in terms of this Code.

6.4 The calculation of royalties payable to an HCP in exchange for Intellectual Property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence.

6.5 For example, royalties paid in exchange for Intellectual Property should not be conditioned upon: (1) a requirement that the HCP purchase, order or recommend any product or medical technology of the Member or any product or technology produced as a result of the development project; or (2) a requirement to market the product or medical technology upon commercialization. Members are strongly encouraged to exclude from the calculation of royalties the number of units purchased, used, or ordered by the HCP and / or member of the HCPs practice.

7. PATIENT REGISTRIES

7.1 With regard to HCP's providing information to registries, remuneration provided must be reasonable and of fair market value, in relation to the work performed.

7.2 Registries may not be disguised as promotion, and should be of scientific and/or healthcare policy merit, and relate to a legitimate and defensive project to obtain data/information. Proof of such bona fide registry data and documentation, including protocols, ethics committee approval and agreements may be called for from time to time by the SAMED Ethics Committee.

7.3 Registries should comply with all applicable laws, including but not limited to privacy protections, the consent of the person whose information it is, the Promotion of Access to Information Act, the National Health Act and the Consumer Protection Act.

8. REIMBURSEMENT FOR INFORMATION AND OTHER ECONOMIC DATA - MARKETING DATA, FORMULARY, MANAGED CARE AND SIMILAR FEES

Members may provide economic efficiency and reimbursement information to HCPs and third party payors of their contractors, employees or administrators regarding Members' products.

8.1 Members may pay for marketing data, formulary listings, managed care, or any other similar information to persons or institutions offering such services or information, provided that such fees:

8.2 1 Are based on a written agreement detailing the exact nature and extent of the service or information for which the fees are paid, which agreement should be available on request or for evaluation in the case of a valid complaint.

8.2.2 The service or information is of legitimate and lawful use to the buyer and such service or information is known to form part of the legitimate business of the seller thereof.

8.2.3 The purchase of the service or information is not a condition for the support of the Member or the Member's product, and is in no way linked to sales value and/or sales volume, targets and/or preferential usage or recommendation of any medical device.

9. FALSE CLAIMS REGARDING REIMBURSEMENT

9.1 Since many healthcare programs (medical schemes, etc) reimburse and pay for Member products, each Member must comply with the applicable laws and regulations[1].

9.2 These laws may impose liability on anyone who knowingly submits a false claim or record in order to obtain payment or to retain money to which they may not be entitled.

9.3 A Member or company that helps, encourages, or causes someone else to make a false claim for reimbursement can also be liable for the false claim. No Member may suggest mechanisms for billing for services that are not medically necessary, or for engaging in any fraudulent practice to achieve inappropriate reimbursement.

[1] i.e. Criminal law and Criminal Procedure Act, as well as Medical Schemes Act and regulations. In future, when devices are registered, the Act that governs the conditions of registration (Medicines Act or similar).

10. CONTRACTING PRIVATE NURSING PRACTITIONERS

In line with Government Notice No. R. 387 as amended, No. R. 866 and No. R. 2490 The South African Nursing Council Rules Setting Out the Acts or Omissions in respect of which the Council may take disciplinary steps (Addendum 2), Members that contract private nursing practitioners are bound by the following:

10.1 If a registered nurse is in the full time employ of a Member, that nurse is considered a company representative - the primary responsibility of the individual being to represent the company. Any interactions with a patient will be subject to the SAMED protocol governing Sales Professionals in the Clinical Environment (see Addendum 3) as well as the professional rules and regulations of the Nursing Council.

10.2 If a nurse is employed or contracted as a nurse by the Member to fulfil the responsibilities of a nurse i.e. as in colostomy products, wound-care, etc, the following apply:

10.2.1 Under no circumstance may the contract be exclusive i.e. the nurse must have the right to also provide competitive products to the patient.
10.2.2 Any agreements that are in place must be in writing and clearly outline what the nurses' responsibilities are.
10.2.3 Any remuneration must be set out in advance and under no circumstances may it be connected to volumes as this would be considered perverse and de facto illegal. Refer to Clause 11 and 13 of Addendum 2.

10.3 Any infringements relating to the above will be dealt with in terms of Part B of this code and may include reporting individuals to the nursing counsel for investigation.

11. PACI PRINCIPLES – PARTNERING AGAINST CORRUPTION INITIATIVE

Samed Members by virtue of this code commit to upholding the PACI Principles for Countering Bribery. In particular by:

11.1 adopting a "zero tolerance" policy on bribery and
11.2 the development of a practical and effective programme of internal systems and controls for implementing that policy.

In practical terms, this will mean either implementing anti-bribery practices based on the PACI Principles, see Attachment, or for companies with established programmes, using the Principles to benchmark existing practice.

PART B: DEALING WITH INFRINGEMENTS OF THE CODES

The overall goal of this procedure is to ensure a complaint-handling process that enjoys public confidence and Member support, and which is effective, lawful and efficient and not a cost-burden for SAMED. This Process applies to dealing with infringements of the SAMED Code of Business Practice.

12. Constitution of the Ethics Committee

12.1 Chairperson

12.1.1 The SAMED Board will appoint an independent chairperson of the Ethics Committee for a period as determined by the Board.

12.1.2 The Chairperson will be responsible to ensure that all complaints and hearings are dealt with speedily and fairly and will be the custodian of the process, ensuring that both the principles of administrative justice, as well as the substance of this code, is preserved and promoted.

12.2 Ethics Committee

12.2.1 The SAMED Board will appoint, from amongst a pool of suitably qualified and experienced persons within the device industry at least four who together with the chairperson, shall be eligible to serve on the Ethics Committee panel.

12.2.2 The pool of suitably qualified persons will be appointed for a period as determined by the SAMED Board and may include employees of companies who are suitably experienced in regulatory affairs, marketing practices, sales practices, law or any other field of relevance to the subject-matter of this Code.

12.2.3 All members of the Ethics committee panel must sign a private and confidential / non-disclosure document and must keep all details relating to the complaint at hand in the strictest confidence, unless the parties agree to specified disclosures.

12.2.4 The composition of the Ethics Committee may differ from case to case, depending on the matter at hand and the potential for conflicts of interest, in which analysis the Secretariat will play a key role throughout the complaint screening process.

12.3 Role of the Secretariat and EO

12.3.1 The EO will fulfil a secretariat function in relation to handling infringements of the Code, including the functions outlined below.

12.3.2 The EO must be present at all hearings, but will not be entitled to participate, or be present when the Ethics committee deliberate. Where the EO is the nominal complainant, she shall be entitled to participate to the same extent as a complainant would be entitled to. A reference to the feminine shall include a reference to the masculine.

13. Lodging a complaint

13.1 Any SAMED Member, customer or regulatory body ("the complainant") may lodge a formal written complaint upon payment of the stipulated fee, set annually by the SAMED Board, and on completion of the prescribed forms.

13.2 The prescribed complaint form has to reveal the following and has to be lodged at SAMED's official place of business:

13.2.1. Name and contact details of complainant (including a named person who will represent the complainant and who could provide further information, if requested). No anonymous complaints will be entertained;

13.2.2. Company employing the complainant, and, if applicable, representative body of complainant;

13.2.3. Field of business of complainant (manufacturer, distributor, doctor, private hospital, etc);

13.2.4. Name of alleged infringing company;

13.2.5. Field in which infringement has occurred (e.g. insulin pumps, orthopedic implants, wound care, etc);

13.2.6. Circumstances of the infringement (what, when, where, how);

13.2.7. Clause(s) within the Code that has allegedly been infringed;

13.2.8. Indication of the proof substantiating such complaint.

13.3 The EO shall within 7 working days of receipt of the complaint, send a copy of the complaint to the respondent and request a formal response within 7 working days from the date upon which the respondent receives the complaint.

13.4 The EO shall within 7 working days from receipt of the response, send a copy of the response to the complainant and invite a reply within 5 working days from the date upon which the complainant receives the response. The reply, if any, will on receipt be sent to the respondent.

13.5 After receipt of the reply, if any, the EO will attempt to facilitate a conciliation of the dispute by following the process set out in clause 15. If the conciliation is not successful the EO will forward the complaint, the response, the reply (if any) ("the documents") and a note advising that conciliation was not successful to the Chairperson of the Ethics Committee for further adjudication as provided for in this Code.

13.6 The complainant may at any time withdraw the complaint except after it has been referred to the Ethics Committee, where after the complaint will be adjudicated on.

14. THE EO AS COMPLAINANT

14.1 The EO shall monitor such conduct by SAMED members as she deems fit to ensure compliance with the Code.

14.2 Should the EO be of the opinion that there has been a breach of the Code, she shall immediately address a written notice, identifying the alleged breach of the Code, to the respondent with a request that it should take such remedial action and steps as may be prescribed and/or to furnish a written response to the EO within 10 working days of receipt of the complaint.

14.3 Should the EO be satisfied that the respondent has satisfactorily dealt or will deal with the complaint, she shall advise the respondent accordingly.

14.4 Should the EO not be satisfied with the response received from the respondent, the EO shall place the complaint before an Ethics Committee by following the procedure provided for in clause 13.5 of the Code. In this instance the EO will be the nominal complainant and no objection fees will be payable.

15. Conciliation

15.1 The EO will facilitate a process aimed at securing an informal resolution of the complaint, through the process outlined below.

15.2 The EO will after receipt of the documents request the parties to convene as soon as possible, offering to facilitate such a meeting in order to resolve the matter. In the event of the EO being the nominal complainant, she will request the respondent to meet with her in order to resolve the matter.

15.3 Any resolution to the matter should preferably be made in writing, and forwarded to the EO in order to close the file on the complaint. However, the EO shall be entitled, in the absence of a written resolution, to determine whether the circumstances relating to the matter evidences a resolution of the dispute and that the file should be closed. A resolution may, for example, entail an acknowledgement that the complaint is not substantiated, that the complaint is based on factual inaccuracies or a misunderstanding, an acknowledgement that the conduct does violate the Code, or parts thereof, or an agreement that the conduct will be modified or ceased.

15.4 Should the parties fail to reach an agreement within 14 days of being requested to meet the complaint will proceed to a hearing.

15.5 All information relating to the complaint and the resolution thereof will be confidential, unless the parties agree to the disclosure of specific details, e.g. an agreement that a particular practice will be stopped.

16. Pre-hearing procedure

16.1 Within 7 days after receipt of the documents, the Chairperson of the Ethics committee will consider whether the complaint has merit or not. Should it be considered that a complaint has no merit (for example is frivolous, vexatious or malicious), the complaint will be dismissed and the stipulated fee will be forfeited. Should the complaint be found to have merit (i.e. be valid), the Chairperson will request the EO to constitute and appoint an Ethics Committee to adjudicate on the complaint. The Ethic Committee shall consist of the Chairperson and at least one other person. The EO shall ensure that no member appointed to the Ethics Committee shall have any direct or indirect interest in the matter adjudicated upon.

16.2 Where the EO is the nominal complainant, the Chairperson of the Ethics Committee shall constitute and appoint the Ethics Committee.

16.3 Copies of the documents shall be made available to the appointed members of the Ethics Committee by the EO.

16.4 The Chairman will advise the EO of the date of the hearing and shall request the EO to advise the complainant and the respondent in writing of the date and venue for the hearing.

16.5 All correspondence will be held in confidence and no appointed member of the Ethics Committee may enter into discussion or correspondence with either the complainant or the respondent.

17. At the Hearing

17.1 Both the complainant and respondent may be present at the hearing. In the event of the parties being juristic persons, they will be represented by an official of the juristic person. The parties shall not be entitled to have legal representation unless the Ethics Committee, having regard to, inter alia, the complexity of the matter, the legal issues involved, the serious nature of the matter and the penalty which may be imposed, in its sole discretion determines otherwise. In such case the respondent shall be entitled to legal representation by a practising attorney or advocate or both. Should the respondent be allowed legal representation, the complainant shall also be entitled to be represented by a practising attorney and/or practising advocate.

17.2 Should any party so request and provide substantiation for such a request, the hearing may, in the absolute discretion of the Ethics Committee be conducted in camera.

17.3 The complainant has the right to present the complaint to the Ethics Committee.

17.4 The respondent has the right to present the case in response to the complaint.

17.5 Both parties have the right to present evidence through oral statements or witness testimony, or to hand other evidence to the Ethics Committee and the other party has the opportunity to respond to such evidence being presented.

17.6 The Ethics Committee may ask questions during the presentation of either party's case and/or question witnesses or request for additional information or the substantiation of information.

17.7 The Ethics Committee may in its discretion call any person as an expert, to present evidence in person or in writing.

17.8 The Ethics Committee will attempt to conclude the hearing within one working day, but the Ethics Committee may adjourn a hearing on the substantiated request of either party, or in its sole discretion, whether to obtain more information or to ensure a fair hearing.

17.9 The Ethics Committee may determine its own procedure and the timeframes stipulated in this Code may be deviated from if the circumstance so dictate.

18. After the hearing

18.1 The Ethics Committee must make a substantiated finding within 7 days after the hearing, and must provide such finding and the reasons for the finding in writing to the EO, who will provide a copy of the finding to both parties.

18.2 The Ethics Committee will attempt to reach its finding by consensus, failing which the Committee will vote on the matter, and, in the case of a tie the chairperson will have the casting vote.

18.3 The confidentiality referred to in this Chapter of the Code does not extend to the EO / Secretariat making a brief summary of the facts of the case and the finding, as such findings then become examples of violations, or conduct acceptable under the Code.

18.4 In cases of extreme and/or repeat violations of the Code, the confidentiality rights of the respondent will give way to the public interest, in ensuring that such violations do not occur again, or that patients or clients are protected.

19. Costs

19.1 Each party will bear its own costs, and no costs will be recoverable from the other party.

19.2 Member companies whose employees are nominated will bear the costs of such employees participating in the Ethics Committee (e.g. time off at work and travel to the hearing).

19.3 SAMED will cover all costs relating to the venue and refreshments required to conduct a proper hearing.

19.4 A reasonable honorarium may be paid to any expert asked by the Ethics Committee to provide additional information to the Committee, in consultation with the SAMED EO and SAMED Chairperson.

19.5 The chairperson of the Ethics Committee will be remunerated at a fee negotiated between the Board and the person to be appointed by the Board.

19.6 All fines imposed in terms of this Code will be dedicated to activities relating to the Code, i.e. the costs associated with hearings, education campaigns, etc.

19.7 Members who terminate their Membership of SAMED prior to, during, or after the initiation of an investigation, the hearing or an appeal, shall still be liable for payment of any costs incurred during the process.

20. Sanctions

20.1 Should the Ethics Committee find that the respondent has breached the Code the Ethics Committee may impose the following sanction on the respondent, which sanctions may be imposed together or as a single sanction and parties may, during the hearing, make submissions as to whether a sanction should be imposed, and the appropriateness and proportionality of such a sanction:

20.1.1 Instructing the respondent to immediately cease the specific conduct;

20.1.2 A letter of censure and an order to comply with the Code;

20.1.3 A fine, the sum of which as may be considered appropriate by the Ethics Committee in the circumstances depending on *inter alia,* the gravity of the offence, its impact on patients, doctors and clients, whether the respondent has been a repeat-offender of the Code, the impact of the violation on the reputation of the device industry and SAMED, the deterrent value of the fine, the value of the deal or violating conduct;

20.1.4 That the respondent furnishes a written undertaking within a stipulated time period that the respondent will avoid similar breaches of the Code in the future;

20.1.5 That the respondent publicly apologises and/or publicly withdraws the materials or undertakes to cease the conduct;

20.1.6 That the respondent pays such costs and expenses relating to the hearing as the Ethics Committee considers just and equitable in the circumstances.

20.1.7 That, if the severity of the violation so warrants, that the name of the respondent is published to the SAMED Membership;

20.1.8 A recommendation to the SAMED Board to expel the respondent, following the procedure stipulated in the SAMED Constitution;

20.1.9 The Ethics Committee may, in the absence of an appeal, also refer the matter to any other body with an interest and jurisdiction in the matter, including but not limited to the Regulatory Authority responsible for device and IVD regulation and device or IVD establishment registration, the Health Professions Council of SA, the Nursing Council, Pharmacy Council or other professional body, the Hospital Association of SA, the Council for Medical Schemes or the Department of Health;

20.1.10 The Ethics Committee may make an order that the stipulated fee (provided for in clause 13.1), or any portion thereof, be forfeited or be refunded as determined by the Ethics Committee having regard to the outcome of the hearing;

20.1.11 Any other order as may be considered appropriate to the Ethics Committee in the circumstances.

21. Appeal Process

21.1 The SAMED board will appoint, from amongst a pool of suitably qualified and experienced persons within the device industry, at least four persons who shall be eligible to serve on the Appeal Panel. The SAMED board shall also appoint such senior advocates who have indicated that they will be willing to serve as members of the Appeal Panel.

21.2 All members of the Appeal Panel must sign a private and confidential / non-disclosure document and must keep all details relating to the complaint at hand in the strictest confidence, unless the parties agree to specified disclosures.

21.3 There shall be no appeal against:

21.3.1 a decision by the Chairman of the Ethics Committee to dismiss the complaint as provided for in clause 16.1;

21.3.2 any decision of the Ethics Committee where the party wishing to lodge an appeal was legally represented before the Ethics Committee.

21.4 An appeal against a decision by the Ethics Committee shall lie to an Appeal Board and to no other body. All decisions, penalties, rulings, determinations or findings of an Appeal Board shall be final and binding on the party or parties concerned.

21.4 Should either the complainant or the respondent wish to appeal the finding, decision or penalty imposed by Ethics Committee ("the appellant"), the appellant shall give notice in writing of his intention to appeal within 7 working days from the date on which the finding, decision penalty to be appealed against has been communicated to him. The notice of intention to appeal shall be addressed to the EO and shall be delivered within the prescribed time limit to the EO.

21.5 Every notice of intention to appeal shall be accompanied by the appeal fee prescribed by the SAMED board.

21.6 Once an appeal has been lodged, the EO shall:

21.6.1 as soon as possible thereafter make a copy of the record of the ethics hearing to which the appeal relates available to the appellant.

21.6.2 advise the other party (hereinafter referred to as the defendant) that an appeal has been lodged and also furnish the defendant with the copy of the record.

21.7 The appellant shall lodge, in writing, a notice of appeal within 10 working days, from the date on which he is notified that the transcript of the ethics hearing is available. The notice of appeal shall set out the penalty, decision or finding appealed against and the grounds of such appeal.

21.8 The notice of appeal shall be lodged with the EO. On good cause shown, the period for lodging a notice of appeal may be extended by the EO, on receipt of a written application from the appellant, which application shall be lodged within the time period allowed for the lodging of the notice of appeal.

21.9 Should a notice of intention to appeal or notice of appeal not be lodged within the prescribed time periods, the right of appeal or the appeal as the case may be shall lapse, provided that the EO may, on written application to her, in her sole discretion and on such terms and conditions as she may determine, condone the late lodging and reinstate any appeal which has lapsed.

21.10 Where an appeal has been lodged, the defendant may within 10 working days after being provided with a copy of the appellant's notice of appeal, lodge a written response with the EO. On good cause shown, the period for lodging a response may be extended by the EO, on receipt of a written application from the defendant, which application shall be lodged within the time period allowed for the lodging of the response. A copy of such response by the defendant, if any, shall be furnished to the appellant who shall be entitled to reply thereto within 5 working days.

21.11 An appeal may be withdrawn by the appellant at any time before the appeal is referred to the Appeal Board by the EO, in which case the appeal fee will be forfeited. Once the appeal has been referred to the Appeal Board the appeal cannot be withdrawn and will be adjudicated on.

21.12In the event of the EO being the nominal complainant, appellant or defendant, the discretion to extend the time periods will be delegated to the Chairman of the Ethics Committee which made the ruling forming the subject matter of the appeal.

22. APPEAL HEARINGS

22.1 Once the process set out in clause 21 has been completed, the EO will forthwith appoint an Appeal Board consisting of at least three members from the persons listed on the Appeal Panel, one of which shall be a senior advocate. The EO shall document the substantiation for their selection. Pending the appeal hearing, the EO shall keep the identity of the appointed members confidential. Where the EO is the nominal appellant or defendant, the Chairman of the Ethics Committee shall appoint the Appeal Board.

22.2 The quorum for an Appeal Board shall be three. The Chairman shall not have a casting vote.

22.3 Should the number of members of an Appeal Board fall below the quorum stipulated in the Code then the proceedings before that board shall be a nullity and another Appeal Board may be constituted to hear the appeal de novo.

22.4 Save where otherwise provided in the Code, an Appeal Board, when hearing an appeal, shall adopt such procedures as it, in its sole discretion, may determine. The appeal will be decided on the record of the Ethics hearing and the representations filed by the parties. Only in exceptional circumstances should the Appeal Board call on the parties to appear before it to argue the appeal. In such a case the appellant shall be entitled to appear before the Appeal Board to argue his appeal but shall not be entitled to have legal representation unless the Appeal Board, having regard to, inter alia, the complexity of the matter, the legal issues involved, the serious nature of the matter and the penalty which had been imposed, in its sole discretion determines otherwise. In such case the appellant shall be entitled to legal representation by a practising attorney or advocate or both. Should the appellant be allowed legal representation, the defendant shall also be entitled to be represented by a practising attorney and/or practising advocate.

22.5 The appellant and the defendant t (and their respective legal representatives, if any) shall be bound by and confined to the record of the Ethics hearing and shall not be entitled to introduce new evidence save with the permission of the Appeal Board, which may determine such matter in its sole discretion and on such terms and conditions as it may deem fit.

22.6 The operation of the finding, penalty or decision of the Ethics Committee concerned shall be suspended:

22.6.1 during the 7 day period referred to in clause 21.4; and/or

22.6.2 when a notice of intention to appeal has been lodged, pending the final determination of such appeal by an Appeal Board, or the lapsing of the appeal or the withdrawal thereof.

23 POWERS OF AN APPEAL BOARD

23.1 An Appeal Board on hearing an appeal, shall have the powers:

23.1.1 to allow the appeal;

23.1.2 to dismiss the appeal;

23.1.3 to substitute any finding or decision as it deems fit or substitute such sanction as it deems fit, including any amended penalty;

23.1.4 to make such order as in its opinion the circumstances may require including an order to remit the matter for the hearing of further evidence or an order for the hearing de novo;

23.1.5 to hear further evidence or receive any documents on such terms and conditions as it in its discretion may decide;

23.1.6 at any time to order a Party to pay all or a portion of the actual costs and other expenses reasonably incurred by SAMED in connection with an appeal or any postponement thereof, in addition to any other sanction, if it is of the opinion that such order is warranted and to determine the amount of such costs and other expenses;

23.1.7 to order that the prescribed appeal fee, or any portion thereof, be forfeited or be refunded as it may determine having regard to the outcome of the appeal;

23.1.8 an order that the matter be reported to any other body with an interest and jurisdiction in the matter, including but not limited to the Regulatory Authority responsible for device and IVD regulation and device or IVD establishment registration, the Health Professions Council of SA, the Nursing Council, Pharmacy Council or other professional body, the Hospital Association of SA, the Council for Medical Schemes or the Department of Health;

23.1.9 to make such rulings as it in its sole discretion shall determine.

23.2 An Appeal Board, in addition to any of the powers set out above, shall be entitled to order that the outcome of the appeal hearing be published in such publications, including newspapers, as it may determine in its sole discretion.

24 Powers of SAMED

24.1 SAMED may cancel or refuse Membership to any company that:

24.1.1. is unwilling to commit to the standards and values reflected in the code and/or

24.1.2. fails to conduct its affairs in a manner consistent with the code.

24.2 Such cancellation or refusal of Membership shall be made only after review by the SAMED Board of Directors, and in line with the provisions of the Constitution.

PART C: GUIDELINES

1. General

- **Question 1**

  Why did SAMED develop a code of business practice? How does this Code relate to the Code promulgated in terms of the 1997 and 2008-amendment to the Medicines and Related Substances Control Act? How does this Code relate to other Policy documents, such as the HPCSA's Perverse Incentives Policy or the SA Code of Practice for the Marketing of Health Products?

  SAMED's Code reflects the unique interactions between medical technology companies and HCPs. Distinguishing features in SAMED's Code arise primarily from the fact that Members interact with HCPs because of the complexity of medical technology and the importance of having HCPs understand how to use the technology safely and effectively. SAMED's Code of Business Practice deals with business practices unlike that of the SA Code of Practice for the Marketing of Health Products that deals with Marketing practices.

  The SAMED Code aims to be in line with other applicable Policy documents that bind health professionals, such as the 'Guidelines and Ethical Rules of Conduct for Practitioners Registered under the Health Professions Act and the HPCSA Policy on Undesirable Business Practices. See www.hpcsa.co.za

- **Question 2**

  Who are "HCPs"? Does the term include non-clinical people who make product-purchasing decisions? Does it include decision-makers within Group Purchasing Organisations?

  The term "HCP" includes: individuals, entities, their employees or employers, their agents or other delegates, and includes, but is not limited to persons registered with the Health Professionals Council, Allied Health Professions Council, the Nursing Council, the Pharmacy Council or, an institution registered at the Department of Health or other regulatory or organisational body, such as a health facility, and who purchase, lease, recommend, use, maintain, arrange for the purchase or lease of, Members' medical technology products in South Africa.

  This includes both clinical and non-clinical people who make product-related decisions. It also includes decision-makers within group purchasing organisations (GPOs). This is a broad definition, intended to encompass anyone with material influence over purchasing, utilisation and similar decisions.

  Other examples of entities that fall within the definition of "HCP" are: The Board of Healthcare Funders, Private and Public Hospitals, Medical Schemes or Funders, Council for Medical Schemes, Laboratory and Pathology technicians.

Note that there may be laws and other codes applicable to relationships with HCPs, including relationships with government employees e.g. The Foreign Corrupt Practices Act.

- **Question 3**

  Are combination products covered by the Code?

  Yes, interactions related to combination products (e.g. devices containing medicines) are covered by the Code.

- **Question 4**

  Does the Code address arrangements between a Member and an HCP relating to licensing a new medical technology to the Member?

  Interactions relating to product development and intellectual property would be subject to the general principle that Members shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful or unethical inducement in order to sell, lease, recommend, use, maintain or arrange for the sale, lease, or prescription of, their products.

2. Reimbursement support progams

- **Question 5**

  Is it appropriate to demonstrate that a product can be used in an economically efficient manner?

  It may be appropriate for Members to provide accurate information relating to the costs, savings and revenues associated with the use of a particular product.
  Without this information, it may be difficult for an HCP to properly evaluate whether it is economically feasible or desirable to purchase any particular product.

3. Payment for shelf space

- **Question 6**

  Is it acceptable to pay for shelf space?

  It is not acceptable to pay for shelf or storage space in an HCPs practice, hospital or hospital group warehouse, excluding retail pharmacies.

4. Paying an HCP to use/sell my product

- **Question 7**

Is paying a nurse employed or contracted as a nurse by my Company, a commission to use / sell my product considered perverse?

Yes

- **Question 8**

Can a HCP be reimbursed by a member for cleaning and packing a loan set at the place of their employ ie a theatre nursing sister?

No - This would be regarded as inappropriate to pay an HCP not in the employ of the member – member companies must train the hospital staff in the management of their loan sets. Movement of loan sets must be managed by local courier companies or by the member themselves.

5. Employee attendance in operating room / clinical environment

- **Question 9**

May a company representative who is a registered Theatre Sister work in a hospital after hours?

Company representatives may not work as HCP's in their spare time unless this is known and agreed to by the Company. Guidance should be sought from DENOSA or SANC and the hospital policy will prevail.

- **Question 10**

May company representatives take / wear their own / company branded overshoes and / or theatre clothes into theatre?

Company representatives may only wear such items if they are appropriate and have been approved by the facility.

- **Question 11**

What should a company representative do should a hospital group / healthcare professional ask the representative to obtain patient consent?

Under no circumstances may a company representative obtain consent from patients. This is the doctor's responsibility.

- **Question 12**

May a company representative touch a patient whilst doing product training?

No, regardless of whether they are a registered nurse or not, a company representative may not touch a patient under any circumstances even if demonstrating / training a product.

6. Code Binding in other countries

- **Question 13**

Is the Code binding on those Members who sell products in other countries e.g. Angola etc.

No, however should the Member sell or engage with a South African HCP outside of South Africa, the SAMED Code will be applicable.

- **Question 14**

Does the SAMED Code offer legal advice?

No. The Code is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. All Members have an independent obligation to ascertain that their interactions with HCPs comply with all current laws and regulations.

- **Question 15**

Will SAMED provide advice on how specific provisions of the Code would apply to specific practices that a Member is contemplating?

Yes. Members are at liberty to address any questions about specific practices to the SAMED Code Advisory Committee. Note, the SAMED Code Advisory Committee bears no responsibility for the advice provided should the Member fail to fully disclose all details / specifics relating to the contemplated practice.

- **Question 16**

Does the Code govern the actions of Members' agents, distributors and Associate Members of SAMED?

Yes. As the code states, Members will communicate the Code's principles to their employees, agents, dealers and distributors with the expectation that they will adhere to the Code. It is important that Members inform these entities of any revisions to the code and that they are made aware of the ethical business practices reflected in the Code's provisions.

7. Handling infringements and enforcement of the Code

- **Question 17**

  What is the current fee that must be paid when lodging a complaint with regard to a possible contravention of the code?

  R2500 incl vat

PART D: COMPLAINT LODGING FORM

SAMED Code of Business Practice Complaint Lodging Form

Date: _____

1	Name of complainant:	
2	Representative body or company of complainant:	
3	Name of alleged infringing company/person:	
4	Provision of the SAMED Code that has allegedly been infringed:	
5	Field in which infringement has occurred (e.g. cardiology, wound care, orthopaedics etc):	
6.1	Circumstances of the infringement: What:	
6.2	When:	
6.3	Where:	
6.4	How:	
7	Supporting evidence, where available:	

Name: _____ Designation: _____

Company: _____ Signed: _____

PART E: ADDENDUMS

Addendum 1

SAMED Policy and Procedure - Transparent Invoicing Model

Issue Date: 13 September 2007
Updated 14 April 2008

Prepared by:

Tanya Vogt (EO of SAMED)

And

Approved by the SAMED Board of Directors

Important Note:

This document is to be initialed on all pages, by the EOO and/or duly designated representative and a signed copy faxed to the SAMED offices at fax nr: 011 467 1697

SAMED POLICY AND PROCEDURE REGARDING A TRANSPARENT INVOICING MODEL

1 Preamble:

As a result of the changing regulatory environment in South Africa and its impact on the provision of affordable health care in the country, the need arose for the South African Medical Device Industry Association (SAMED) to develop a policy to transform business practices within the medical device industry.

In order to establish such a policy, it became necessary that SAMED constitute a committee – The Code of Ethical Business Practice portfolio committee, which was tasked with developing a policy to address transparency within the health care industry. The **Transparent Invoicing Model**, to which this document refers, was workshopped with SAMED members on 31 August 2007. In addition, SAMED has consulted widely with key stakeholders including, but not limited to the various hospital groups and funders to ensure the successful implementation of this policy.

All members of SAMED are expected to adhere to this Model and the principle of presenting transparent invoices.

In addition, SAMED members must ensure their compliance with related legislation and/or regulation, and in particular must ensure that, in any discussion with any individual, institution; body and/or association, that their representations are complaint with Competition Law (see the Competition Act [Act No. 89 of 1998]).

2 Purpose:

To ensure that members provide accurate, transparent and responsible billing information to HCPs, reimbursement authorities and other payors members .

3 Definitions:

3.1 **Customers:** customers may include, but not be limited to: hospital groups, independent hospitals, health professionals etc

3.2 **Inception date:** that date by which all suppliers of medical devices shall commence with the transparent invoicing model and which is set as 1 October 2007.

3.3 **Maximum List Price:** that price which is the supplier's benchmark price and the maximum price at which the item will be sold at to a customer.

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3.4 **NAPPI code:** the National Pharmaceutical Product Interface code, being that unique code which is allocated by MediKredit to a "medical device" as defined in the Medicines and Related Substances Act 101 of 1965. NAPPI codes are allocated to all reimbursable medical devices, in accordance with MediKredit's NAPPI Code Allocation Policy, to uniquely identify such products using the product description and catalogue number linked to the supplier and associated price thereof. This allows identification of exactly which stent, catheter, cochlear implant etc. is being supplied. Only ONE such code shall apply per product as identified per catalogue number per supplier.

3.5 **Other inducements:** inducements of any nature or form e.g. payment for information or shelf space, supply of bonus or free goods and the like, where such payments are deemed to be perverse..

3.6 **Settlement discount:** that discount which is granted for timeous settlement of an account and which reflects the normal 'cost of money'.

3.7 **Special requests, charitable donations and pro bono supplies:** those devices which are supplied to a customer at a reduced or nil price for special cases such as the indigent or non medical scheme members.

3.8 **Volume discounts:** that discount which may be applied to the Maximum List Price in order to compensate the customer for volume purchasing.

4 The Transparent Invoicing Model:
The Transparent Invoicing Model in regard to the supply of medical devices shall commence by **1 October 2007** by adopting either of the following two transparent invoice models:

4.1. Model One: Nett Pricing Model

The nett pricing model allows for suppliers to invoice each line item at the contracted nett price as per the contract. This model is similar to the public bid system where no volume discount whatsoever is shown on invoice.

Suppliers are encouraged to display the NAPPI code for each product and may also display the settlement discount percentage on the invoice for purposes of transparency.

4.2 Model Two: Discount Model

In some instances, where suppliers are required to indicate their discount from the Maximum List Price to the hospital/hospital group, this may be done provided that the Maximum List Price is clearly indicated and that the discount is shown as a deduction from the Maximum List Price. The result should be that the nett price is transparent on the invoice.

Suppliers are encouraged to display the NAPPI code for each product and may also display the settlement discount percentage on the invoice for purposes of transparency.

To summarise:

The supplier shall ensure that the following appear on the invoice when charging their customer:

- Maximum List Price
- Volume discount
- Nett price
- Value added tax
- Total amount payable

4.3 In addition to the above two models, the following may also be reflected on the invoice in order to ensure further transparency:

- NAPPI code
- Settlement discount terms e.g. 2,5% for 30 day settlement from date of invoice/statement

5 Maximum List Price / Nappi Codes:

In line with the affordability aspect of this policy document, SAMED implores its members to use this opportunity (i.e. the move to the Transparent Invoice Model) to review Maximum List Prices and revise these accordingly where possible to maximise cost benefits to the patient. As an association, we are committed to promoting action within our membership to address the spiraling cost of health care in the country. In accordance with this commitment:

5.1 All suppliers of medical devices are required to submit their revised pricing list, as applicable, to MediKredit. The revised Maximum List Price should be based on the maximum selling price per item as identified per catalogue number per supplier.

5.2 In reinforcing the policy governing NAPPI codes, only ONE NAPPI code should be applicable per item as identified per catalogue number per supplier. Where more than one NAPPI code exists for the same item, the supplier shall inform MediKredit of this and request that the duplicate Nappi Code(s) be discontinued with immediate effect.

5.3 Where applicable, the process of submitting the Maximum List Prices to customers shall commence from **1 October 2007 and should be finalised and fully implemented by no later than 31 December 2007.**

5.4 Revised nett price and/or contracted nett prices below the Maximum List Prices can be negotiated between supplier and customer based on inter alia. volume and other criteria determined by each supplier on a free market and competitive basis subject to compliance with the terms and conditions of section 4 of this policy.

6 Other inducements:

6.1 No inducements of any nature or form are to be paid or offered to customerse.g payment for information or shelf space, supply of bonus or free goods and the like, where such payments are deemed to be perverse. Sampling must be in accordance with the provisions of the SA Code for Marketing of Health Products.

7 Special Requests and pro bono supplies:

7.1 In the event of the provision or sale of an item that falls within the category of special requests, charitable donations and pro bono supplies, an invoice must be submitted along with supportive documentation, explaining in detail the reason for such provision or sale.

8 Revisions:

This policy and procedure may be revised from time to time in consultation with all signatories/stakeholders and to ensure compliance with any statutory requirements.

9 Signatories:

Signatories; shall include, but not be limited to:

- Members of SAMED;
- Non members of SAMED;
- Service provider groups;
- Schemes/Funders and;
- Other healthcare professionals.

Signatories shall be published on the SAMED website.

10 Compliance:

This document will be incorporated into the SAMED Code of Business Practice with its policy directives on ethical conduct and professional behaviour and the disciplinary measures which may be instituted against its members.

11 Enquiries:

All enquiries with regard to this policy document are to be submitted, preferably, in electronic format to: tanya@samed.org.za or fax 011 777 7501.

Signed:

I _____ duly authorized and representative of

_____(Company) hereby commit to implementing and adhering to

this policy from this day _____ (date) forward.

Witness _____

Addendum 2

Government Notice No. R. 387	*15 February 1985*
as amended by	
No. R. 866	*24 April 1987*
No. R. 2490	*26 October 1990*

The South African Nursing Council

Rules Setting Out the Acts or Omissions in Respect of Which the Council May Take Disciplinary Steps

The Minister of Health and Welfare has, on the recommendation of the South African Nursing Council, determined that the acts or omissions meant in section 35 of the Nursing Act, 1978 (Act 50 of 1978), are the acts or omissions specified in the Rules set out in the Schedule hereto.

SCHEDULE

CHAPTER 1

Definitions

1. In these rules "the Act" shall mean the Nursing Act, 1978 (Act 50 of 1978), and any expression to which a meaning has been assigned in the Act shall bear such meaning, and, unless the context otherwise indicates-

"advertisement" shall mean any written, illustrated, visual or other descriptive material or verbal statement or reference-

(a) which appears in a newspaper, magazine, pamphlet or other publication;

(b) which is distributed amongst members of the public;

(c) which has been fixed to, or appears on walls, windows or boards; or

(d) which is brought to the attention of members of the public in any other manner whatsoever,

and which is meant to -

(i) promote a specific practice or a specific practitioner's technique or treatment;

(ii) make known a practitioner's professional proficiency or knowledge;

(iii) make known a product or business or institution or organisation of any nature whatsoever, for whatever purpose and in any way whatsoever,

and "advertising" shall have a corresponding meaning;

"bona fide patient" shall mean a patient who has at any time previously been treated by the practitioner concerned;

"section" shall mean a section in the Act.

CHAPTER 2

REGISTERED NURSES

2. Subject to the proviso in section 35, it is hereby determined that the acts or omissions set out in this chapter, are deemed to be acts or omissions in respect of which the council can take disciplinary steps against a registered nurse in terms of Chapter 4 of the Act.

Practice

3. Wilful or negligent omission to carry out such acts in respect of the diagnosing, treatment, care, prescribing, collaborating, referral, co-ordinating and patient advocacy as the scope of his profession permits.

4. Wilful or negligent omission to maintain the health status of a patient under his care or charge, and to protect the name, person and possessions of such a patient, through-

(a) correct patient identification;

(b) determining the health status of the patient and the physiological responses of the body to disease conditions, trauma and stress;

(c) the correct administration of treatment, medication and care;

(d) the prevention of accidents, injury or other trauma;

(e) the prevention of the spread of infection;

(f) the checking of all forms of diagnostic and therapeutic interventions for the individual;

(g) specific care and treatment of the very ill, the disturbed, the confused, the aged, infants and children, the unconscious patient, the patient with communication problems and the vulnerable and high-risk patient; and

(h) the monitoring of all the vital signs of the patient concerned.

5. Wilful or negligent omission to keep clear and accurate records of all actions which he performs in connection with a patient.

6. Purporting to perform the acts of a person registered in terms of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974), and the Pharmacy Act, 1974 (Act 53 of 1974), unless the nurse is also registered in such a capacity.

Advertising

7. (1) Subject to the provisions of subrule (2) a nurse may not-

(a) advertise;

(b) permit his name to be used in a professional capacity in connection with advertising.

(2) The following actions of a nurse are not deemed to constitute advertising:

(a) A communication to a *bona fide* patient concerning change of address, hours of consultation and telephone numbers or the establishment or dissolution of a partnership, provided such communication is addressed to the patient concerned and is enclosed in an envelope;

(b) A communication to another nurse, midwife, medical practitioner, dentist, member of a supplementary health service profession, social worker, hospital, person or institution approved by the council, that he has commenced a practice, provided such communication is addressed to the persons concerned and is enclosed in an envelope;

(c) The entry, in ordinary print, of his name, profession, field of practice, residential and consulting rooms addresses and telephone numbers and the name, profession and field of practice of a partner, in an official telephone directory;

(d) The publication of articles of a health science nature in professional journals and books in connection with health, with mention of his name and professional qualifications;

(e) The divulgence of his views on topics of a health science nature in the lay press or on the radio or television or the holding of a lecture or address for a lay audience, with mention of his name, where such a nurse-

(i) serves in a full-time or part-time capacity in health services or post-secondary educational institutions and is not in private practice; or

(ii) acts as an officer or member of the South African Nursing Association or of the council and on instruction of such association or the council;

(f) the use of a name plate as stipulated in rule 8 or rule 9;

(g) the use of stationery as stipulated in rule 10;

(h) the acts referred to in rule 12(2) or rule 18(3); and

(i) the promotion of the interests of an organisation registered in terms of the National Welfare Act, 1978 (Act 100 of 1978), a professional nursing association or society, a health service at any level of government, an educational service approved by the council and any other organisation, body or institution approved by the council.

Name plates

8. (1) The permanent consulting rooms of a nurse in private practice shall, and the permanent residence of such a nurse may, be indicated only by a name plate as stipulated in this rule, which shall not exceed 360mm x 210mm in size and which shall bear only the nurse's-

(a) title, initials and surname;

(b) registered profession and field of practice;

(c) professional qualification or qualifications the use of which, in the case of such a nurse, is authorised by the council;

(d) telephone number(s); and

(e) hours of consultation:

Provided that where a nurse prefers not to have particulars concerning telephone numbers and hours of consultation indicated on such name plate, a separate plate, not exceeding 360mm x 210mm in size, with the nurse's telephone number(s) and hours of consultation, may be affixed directly below such name plate.

(2) (a) In the case of an itinerant practice the nurse's consulting rooms shall be indicated only by a name plate as stipulated in subrule (1), with the addition of the days and hours of consultation when the said nurse is available at the said consulting rooms.

(b) The further information stipulated in paragraph (a), may be indicated on a separate plate or surface, not exceeding 360mm x 210mm in size.

(3) Not more than one name plate may be displayed at each entrance to a building in which a nurse's consulting rooms are situated and one on or next to the door of such consulting rooms: Provided that a name plate may be affixed to an outer wall or pillar of such building with the prior approval of the council, where such a building does not have suitable facilities for a name plate to be affixed thereto: Provided further that the particulars stipulated in subrule (1) may, with the prior approval of the council, be affixed in a framed area of 360mm x 210mm on a glass window as close as possible to the entrance of the building in which the consulting rooms are situated, where such a building has no facilities for a name plate to be affixed thereto.

(4) Where facilities exist in the entrance hall or on the ground floor of a building in which a nurse's consulting rooms are situated, to indicate the names of tenants, the nurse's title, initials, surname and profession may be indicated in such places.

(5) A plate with the initials and surname of a nurse and a direction indicator thereon, may be displayed in the corridor of the floor where the nurse's consulting rooms are situated.

9. (1) If a nurse takes over the practice of another nurse or if a partner in the practice dies or retires, the name plate of the predecessor concerned, the deceased or the retired partner may be displayed for no longer than 12 months after the date of such take over, death or retirement, during which period the name of the person who has taken over the practice shall appear on such name plate.

(2) If a nurse moves to consulting rooms at a new address, a notice to this effect, mentioning the new address of his consulting rooms, may be displayed at his previous address for no longer than 12 months from the date of such move.

Stationery (including visiting cards)

10. Only the following information may appear on professional stationery:

(a) The name of the nurse and partner, if any;

(b) the registered profession, field of practice and abbreviations in respect of qualifications registered by the council;

(c) addresses and telephone numbers;

(d) hours of consultation.

Canvassing

11. A nurse may not, either personally or through the mediation of an agent or in any other manner, canvass or tout for a patient for himself or for any other person.

Itinerant practice

12. (1) An itinerant practice may be carried on where a nurse renders a complete and satisfactory service to his patients in such a practice on a regular basis.

(2) Such service shall be rendered at least once a month and shall be similar to the service which he renders at the place where he carried on his main practice.

(3) Subject to the provisions of rule 8(2)(a) and (b) a nurse may make his intention to visit a place known to the persons mentioned in rule 7(2)(a) and (b).

Financial interest

13. A nurse may not-

(a) (i) accept or insist on any commission or remuneration, financial or otherwise, from manufacturers of, or dealers in medicines, remedies or any equipment, apparatus, instrument, appliance or material which is used in the course of his practise or prescribed to patients;

(ii) pay or give anybody commission or remuneration, financial or otherwise, or offer anybody anything for the recommendation of patients;

(iii) accept any commission or remuneration, financial or otherwise, from somebody for the recommendation of patients;

(b) share any fees collected for a service, with anybody other than a partner, unless such sharing is commensurate with the extent of such other person's participation in the rendering of such service.

(c) charge higher fees for professional services rendered than any fees prescribed in terms of section 45(1)(r) of the Act.

Certificates

14. (1) A certificate required from a nurse in his professional capacity, may only be issued by such a nurse if, as a nurse, he is convinced, from his personal observation or from what the patient has communicated to him, that the facts stated in such a certificate are correct.

(2) Where such a certificate is issued only on the grounds of the communication of a patient or another person, such fact shall be specifically mentioned in the said certificate.

Professional secrecy

15. (1) Subject to the provisions of subrule (2), a nurse may not divulge any information concerning a patient which has become known to him in his professional capacity.

(2) This rule is not applicable if such information is made known-

(a) with the explicit consent-

(i) of a patient who is of age;

(ii) of the parent or guardian of a patient who is a minor; or

(iii) of the surviving spouse or child who is of age, of a patient who is deceased;

(b) where instructed thereto by a court of law or where a nurse is otherwise lawfully bound thereto;

(c) in the exclusive interest of a patient who is not able to, or is not capable of, granting permission; or

(d) in a professional consultation with anybody involved in the treatment of the patient or, in the exclusive interest of the patient, with somebody else.

Medicines, apparatus and processes

16. No use may be made in a practice of-

(a) any form of treatment, apparatus or process which is secret or claimed to be secret;

(b) any apparatus which upon inspection by the council does not prove to be capable of fulfilling the claims made in respect thereof;

(c) diagnostic and treatment methods which do not comply with the accepted standards as determined by the council from time to time.

Impediment

17. A nurse may not impede a patient or a person properly acting on behalf of a patient, who desires to obtain the advice of or treatment by another person who is authorised by law to advise or treat persons concerning their health, to consult such a person.

Acts and exhibition of certificates

18. (1) Except in case of emergency a nurse may not perform an act-

(a) which does not pertain to his registered profession;

(b) for which he has inadequate training or experience.

(2) A nurse may not-

(a) use consulting rooms connected to or with a corridor to a premises or portion thereof where another business, trade, work or profession than that profession in which he is registered in terms of the Act, is practised or carried on: Provided that the entrance and corridors of a public building in which his consulting rooms are situated, or a connection which may not be used by patients, are not deemed to be an unauthorised connection or thoroughfare;

(b) practise or carry on from his consulting rooms any business, trade, work or profession except the profession in which he is registered in terms of the Act, except with the prior written consent of the council and subject to such conditions as the council may determine; or

(c) share consulting rooms with someone other than a person referred to in rule 19(1)(a), without the prior written consent of the council.

(3) A practitioner may display only the following certificates in his consulting rooms:

(a) Certificates, diplomas and degrees which have a bearing on the profession in which he is registered; and

(b) membership certificates of professional associations with which he is affiliated.

(4) A nurse shall display clearly in his consulting rooms the registration certificate issued to him in terms of the Act.

Co-operation, partnership and service contracts

19. (1) Subject to the provisions of subrule (2), a nurse may not, in the practise of his registered profession-

(a) enter into a partnership or where such partnership already exists at the coming into effect of these rules, other than with the council's approval and subject to conditions which the council determines, maintain it or co-operate with a person who is not-

(i) registered or enrolled in terms of the Act;

(ii) registered in terms of any other act in respect of a profession which is approved by the council in the public interest and with consideration of professional ethics, as an acceptable profession for the purposes of partnership or professional co-operation;

(b) unilaterally and without the approval of the other party, break a contract of service into which he has entered;

(c) refuse or in a deliberate or negligent manner fail to execute any lawful duties for which he has been employed;

(d) support or assist any person in any way in illegal practice or action;

(e) employ somebody to perform nursing acts, who is not registered or enrolled in terms of the Act.

(2) Subrule (1) shall not apply in an emergency.

Tendering

20. A nurse may not tender for a full-time, part-time or any other kind of nursing appointment.

Supersession

21. A nurse may not-

(a) take the place of another nurse or midwife who is in charge of a case in respect of which he acted together with or on behalf of such a nurse or midwife, except with the consent of such nurse or midwife who was in charge of the case originally, unless the consent is refused unreasonably or unless no other nursing, midwifery or medical assistance is available;

(b) take over a case of another nurse or midwife unless he is convinced that the patient or person in charge of the case has notified such nurse or midwife that he no longer requires his services.

Delay in obtaining medical assistance

22. In accordance with the exigencies of the circumstances and the seriousness of the patient's condition, a nurse may not neglect-

(a) to refer the patient for medical care where such care is beyond the scope of practice of the nurse and may not delay such referral;

(b) to do what he can to save a life, to arrest deterioration in the health status of the patient, to prevent deformity or to reduce pain and suffering;

(c) in circumstances where a patient is in the care of such a nurse but the control over the medical treatment of a patient rests with someone other than the nurse, to execute without reasonable grounds any verbal or written prescriptions or any request made to the nurse by that person with regard to the medical treatment of such a patient, or where such prescription or request is not executed, to inform such a person of the non-execution thereof as soon as practicably possible.

Professional reputation of other persons

23. A nurse may not unjustly cast reflection, explicitly or by implication, upon the probity or professional reputation, skill, knowledge, service or qualifications of any person registered or enrolled under the Act or under any other act.

Relations with the council, its members and officials

24. A nurse may not perform any wilful act which is calculated to-

(a) prevent the council, a committee of the council or the registrar from performing a duty which may be lawfully performed by the council, such committee or the registrar;

(b) bring the council or any member or official into contempt or discredit.

Exploitation

25. A nurse may not permit himself to be exploited in a manner detrimental to the public or to professional interest.

Repeal

26. The regulations published under Government Notice R.1650 of 14 September 1973, as amended by Government Notice R.481 of 10 March 1978, are hereby repealed.

CHAPTER 3

REGISTERED MIDWIVES

27. Subject to the provisio to section 35, it is hereby determined that the acts or omissions set out in this chapter, shall be deemed to be acts or omissions in respect of which the council may take disciplinary steps against a registered midwife in terms of Chapter 4 of the Act.

28. Rules 7 to 25 shall *mutatus mutandis* apply to a registered midwife.

29. Wilful or negligent omission to carry out such acts in respect of the monitoring, diagnosing, treatment, care, prescribing, collaboration, referral, co-ordination and patient advocacy as the scope of his profession permits.

30. Wilful or negligent omission to protect the name, person and possessions of a mother and child under his care or charge in the course of pregnancy, labour and the puerperium through-

(a) the correct identification of the mother and child;

(b) the prevention of accidents, injury or other trauma;

(c) the prevention of infection and of the spread of infection;

(d) the checking and monitoring at reasonable intervals of all forms of diagnostic and therapeutic interventions;

(e) the specific care and treatment of the vulnerable, high-risk mother and child, the seriously ill, the disturbed, the confused, the unconscious patient and the mother with communication problems.

31. Wilful or negligent omission to keep clear and accurate records of the progress of pregnancy, labour and the puerperium and all acts which he performs in connection with a mother and child.

32. Failure to comply with the conditions under which he may carry on his profession, as promulgated by Government Notice No. R.2488 of 26 October 1990.

33. Purporting to perform the acts of a person registered in terms of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act No. 56 of 1974), or the Pharmacy Act, 1974 (Act No. 53 of 1974), unless the registered midwife is also registered in such capacity.

CHAPTER 4

ENROLLED MIDWIVES

34. Subject to the proviso to section 35, it is hereby determined that the acts or omissions set out in this chapter shall be deemed to be acts or omissions in respect of which the council may take disciplinary steps against an enrolled midwife in terms of Chapter 4 of the Act.

35. Rules 7 to 25 shall *mutatis mutandis* apply to an enrolled midwife.

36. Wilful or negligent omission to identify health needs and to promote the health of mother and child through such acts and procedures as the scope of his practice permits.

37. Wilful or negligent omission to protect the name, person and possessions of a mother and child under his care or charge through-

(a) the correct identification of the mother and child;

(b) the prevention of accidents, injury or other trauma;

(c) the prevention of infection and of the spread of infection;

(d) the carrying out at reasonable intervals of all observations and interventions while the mother and child are in his care, and the recording thereof.

38. Failure to comply with the conditions under which he may carry on his profession, as promulgated by Government Notice No. R.2488 of 26 October 1990.

39. Purportion to perform the acts of a person registered in terms of the Act, the Medical, Dental and Supplementary Health Service Professions Act, No. 56 of 1974, or the Pharmacy Act, No. 53 of 1974.

Addendum 3

SAMED Protocol on Member Company Employees' attendance in an Operating Room/ Clinical Environment

All SAMED member companies must make this protocol a condition of employment for any personnel who might be present in an Operating Room/Clinical Environment.

Addressed to:

SAMED Member Company Employees who enter an Operating Room/Clinical Environment.

Prior to Entering an Operating Room/Clinical Environment

You must complete relevant training on operating room/clinical environment protocol prior to entering any operating room/clinical environment.

You are expected to know and follow the relevant policies and procedures of the facilities you visit. In some instances this may require documentation that you meet certain requirements related to:

- your current personal medical status[2]
- your training with respect to safety protocols around blood borne pathogens,
- operating room/clinical environment procedures and requirements.

Requests for documents verifying such information related to training should be made to your company management. Any documentation regarding personal medical status must be provided directly to the facility by you, in line with any legal requirements or restrictions.

It is incumbent upon you to ensure that personal liability cover is in place.

It is incumbent upon you to ensure that a discussion has taken place with the surgeon confirming that he/she has received patient consent for you to be present.

It is incumbent upon you to ensure that you have signed a confidentiality agreement with the hospital concerned.

In the Operating Room/Clinical Environment

You may only enter an operating room/clinical environment in accordance with permission from appropriate members of the medical staff of the facility. You are expected to wear appropriate attire, as provided by/or approved by the facility. It remains the responsibility of the facility to provide appropriate clothing. However if this is not possible then the facility must provide authorization for you to provide your own appropriate attire.

[2] This applies primarily to communicable diseases e.g. TB, hepatitis B etc. not those conditions you need not disclose by law

You should be prepared to advise on technical questions related to the assembly and operational performance of Company products consistent with the labeling and instructions for use.

You may not provide clinical diagnostic advice, surgical advice or recommend treatment, even as the result of a direct request from the surgeon, operating room staff, or any other Healthcare Professional.

When acting on behalf of your company, company products may not be used and/or applied directly to a patient by you even if you hold appropriate certification/licenses, You may not deliver patient care or perform medical services of any type, even if you possess an appropriate medical license/certification.

Your purpose in the operating room/clinical environment is to provide expertise relating to the preparation, assembly and use of instrumentation / devices which must be facilitated by communicating with the appropriate healthcare professional performing the procedure.

You may not have any hands on contact with the patient or any part of the patient during surgery or clinical event.

If there is any doubt about compliance with this protocol and involvement in the operating room/clinical environment then you should seek guidance from your company management before the procedure, and not enter the room.

Indemnification of Liability

Notwithstanding the fact that you have followed all these procedures, it is important that you are aware that this will in no way indemnify you from any liability in the event that any action is taken by either, the hospital, patient or healthcare professional.