HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

PROFESSIONAL BOARD FOR MEDICAL TECHNOLOGY

Document Name	Guidelines to enter into Private Practice for Medical Technologists/Medical Laboratory Scientists
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CHANGE HISTORY			
Version	Date	Change request	Change Comment
1		In the absence of the policy or the regulations for Medical Technology private practice in the interim this guideline will be used to temporarily guide the Medical Technologist and Medical Laboratory Scientists s practitioners wishing to conduct private practice;	First approval of the guidelines

Health Professions Council of South Africa

Contents

1. INTRODUCTION

The HPCSA together with the 12 Professional Boards under its ambit, is established to provide control over the education, training and registration for practicing of health professions registered under the Health Professions Act 56 of 1974.

Its mission is to protect the public and guide the professions. In order to do that, the Council ensures that practitioners uphold and maintain professional and ethical standards within the professions and ensures the investigation of complaints concerning practitioners and to ensure that disciplinary action is taken against persons who fail to act accordingly as prescribed in section 41 of the Health Professions Act 56 of 1974.

These guidelines must not be read in isolation but be read in conjunction with the rules and other ethical booklets of the HPCSA, which include but are not limited to:

i. Booklet 1: General Ethical Guidelines for Healthcare Professions.

ii. Booklet 2: Ethical and Professional Rules of Conduct.

iii. Booklet 4: Seeking Patients' Informed Consent: The Ethical Considerations.

iv. Booklet 5: Confidentiality: Protecting and providing information.

v. Booklet 9: Guidelines on Keeping of Patient Records.

vi. Booklet 11: Guidelines on Overservicing, Perverse Incentives and related matters.

vii. Booklet 12: Guidelines for the management of health care waste.

2. PURPOSE

To guide practitioners registered under the ambit of the board on the process to apply for approval by the MTB to own and operate a private practice, the applicable legislations, and ethical professional conduct expected of registered practitioners in professional practice.

To assist the Medical Technologists and/or Medical Laboratory Scientists who are registered with the HPCSA and approved by the MTB to open the private practice with the following:

- Laboratory Requirement
- Framework on writing a business plan.
- Setting up quality management systems for the laboratory
- Health and Safety
- Business administration

Enable Medical Technologists in Private Practice to understand and apply the HPCSA's Regulatory Framework, Ethical Rules and Guidelines and the Scope of Profession.

3. ACRONYMS

HPCSA - Health Professions Council of South Africa

MTB – Professional Board for Medical Technology

SMLTSA – Society of Medical Laboratory Technology of South Africa

BHF – Board of Health Funders

ICD 10 codes – The International Classification of Diseases

CC - Close Corporation

4. LEGISLATIVE FRAMEWORK

All Medical Technologists/Medical Laboratory Scientists in private practice should demonstrate an understanding of the relevant Acts and regulations.
All Acts and Regulations of the HPCSA are available on the HPCSA website (www.hpcsa.co.za)

4.1 Health Professions Act 56 of 1974

In terms of Section 15A of the Health Professions Act 56 of 1974, the professional boards are mandated to maintain and enhance the dignity of the relevant health profession and the integrity of the persons practicing such profession; and to guide the relevant health profession or professions to protect the public.

4.2 General Ethical Guidelines for the Healthcare Professions (Booklet 1)

The general ethical guidelines contain value-oriented principles and expresses the most honourable ideals to which members of the healthcare profession should subscribe to in terms of their conduct. The term “profession” means “a dedication, promise or commitment publicly made”. 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.

Being 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.

4.3 Ethical and Professional Rules of the Health Professions Council of South Africa (Booklet 2)

The Health Professions Council of South Africa, in consultation with the professional boards, has, under section 49 of the Health Professions Act, 1974 (Act No. 56 of 1974), made the rules of conduct which registered practitioners are to comply with in the course of their professional work.

Failure by a practitioner to comply with any conduct determined in these rules or an annexure to these rules shall constitute an act or omission in respect of which the board concerned may take disciplinary steps in terms of Chapter IV of the Act. These rules are reproduced in this booklet.

4.4 HPCSA Policy on Business Practices

To guide the professions on matters related to business models, ownership, employment, and involvement of corporate entities in professional practice, the HPCSA's developed the Policy on Business Practices to provide guidance on business models that are acceptable for registered practitioners, and what is regarded as undesirable business practices.

4.5 The HPCSA regulations relating to the scope of profession/practice for Medical Technologists

All Medical Technologists may only practice in the field in which they are qualified and registered in with the HPCSA.

All results reported should be signed out by a registered medical technologist in the applicable discipline.

4.5.1 Performance of Professional Acts as provided for in Ethical Rule 21:

A practitioner shall perform, except in an emergency, only a professional act -

(a) for which he or she is adequately educated, trained and sufficiently experienced; and

(b) under proper conditions and in appropriate surroundings.

5. ACCEPTABLE BUSINESS MODELS AND PRACTICES

The following business models are acceptable for registered practitioners:

a. Solo Practice
b. Partnerships/Groups/Organisations
c. Associations
d. Personal liability companies (incorporated practices – Inc.)
e. Franchises (subject to compliance with the ethical rules of conduct).

Any arrangements with unregistered entities or persons to provide administrative and other non-professional services must be aligned with the ethical rules of Council.

Direct or indirect corporate ownership of a professional practice by a person other than a registered practitioner in terms of the Act is not permissible.

6. PARTNERSHIP AND ASSOCIATION (ethical rule 8)

A practitioner shall practise in partnership, association or as a juristic person only within the scope of the profession in respect of which he or she is registered under the Act (ethical rule 8 (3).

The restriction in Rule 8(3) does not apply to the following professions: A Pathologist forming an incorporated practice (Personal Liability Company), partnership or association with a Medical Technologist.

7. NAMING OF PRACTICE (ethical rule 5)

A practitioner shall use his or her own name or the name of a registered practitioner or practitioners with whom he or she is in partnership or with whom he or she practises as a juristic person, as a name for his or her private practice.

“(2) A practitioner referred to in subrule (1) may retain the name of such private practice even if another practitioner, partner of such partnership or member of such juristic person is no longer part of such private practice: Provided that the express consent of the past practitioner or, in the case of a deceased practitioner the consent of the executor of his or her estate or his or her next-of-kin, has been obtained.

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

8. REQUIREMENTS FOR REGISTRATION IN THE CATEGORY PRIVATE PRACTICE

a. Practitioners who hold the qualification Bachelor of Health Science in Medical Laboratory Scientist and Diploma in Biomedical Technology and has passed the Medical Technologist Board examination can apply to register for a Private Practice.
b. They may apply to the HPCSA after two years post registration in the discipline of which they qualified in.
c. Each application for approval to conduct a private practice has to be considered by the Professional Board.
d. The applicant will be notified whether his/her application has been successful.

9. PROCESS OF APPLYING FOR PRIVATE PRACTICE

The following **ORIGINAL** documentation must be submitted to the HPCSA or be uploaded under your profile on the practitioner’s portal on the HPCSA website:

a. The application form (Form 133) duly completed;

b. **AN ORIGINAL LETTER** from your employer confirming that you have at least two (2) years post registration experience in medical technology in the particular category;

c. Certified Extract certificate from the register for purposes of registration of a practice number at the Board of Healthcare Funders of South Africa. Please also reflect your MT / MLS registration number on the deposit slip.

d. Proof of payment of annual fee

e. Proof of compliance to CPD requirements

Banking details are as follows:

ABSA Bank Arcadia
Branch code: 334945
Account number: 061 00 00 169

TURNAROUND TIME FOR COMPLETING THE APPLICATIONS FOR REGISTRATION IN PRIVATE PRACTICE CATEGORY.

The response will take 6 – 7 weeks

Please note the following:

a. In terms of the ethical rules, you may only practice in your personal capacity and may **NOT** link any name such as hospital, clinic, etc. to your practice name.

b. You may reflect the category of registration such as Microbiology, Clinical Pathology etc. **Examples: Ms Dorothy Daniels Medical Technologist or D Daniels Medical Technologist (Microbiology) etc.**

c. Medical Technicians may not enter into private practice.

10. LABORATORY REQUIREMENTS

Minimum consideration for opening a private practice:

a. Building and the location
b. Personnel
c. Equipment and reagents
d. Supplier list
e. Laboratory Information System
f. Billing Platform
g. Hazardous waste services
h. Insurance and Risk Management
i. Test menu offering
j. Familiarisation with funders and their requirements

11. FRAMEWORK FOR WRITING A BUSINESS PLAN

a. Security system

b. Legal support
c. Account's support
d. Marketing
e. Test Menu Offering
f. Equipment
g. Consumables
h. Stationery
i. Referral laboratory arrangements
j. Statutory compliance e.g. SARS, UIF etc.
k. Quality Management System

12. QUALITY MANAGEMENT SYSTEM

Good Laboratory practice and quality assurance programmes should be in place and evidence of this should be available on request.

It is important to note that:

a. the public and other medical aid entities may request to inspect the premises and billing procedures should a complaint be raised against a certain practice.
b. Such inspection will be done through the HPCSA Inspectorate Office.
c. The implementation of good quality management system and compliance to all relevant legislation and policies is crucial.
d. SANAS ISO 15189 check list is the best guideline for the implementation of good quality management system.
e. Depending on the size and the financial standing of the practice, the laboratory can apply for SANAS accreditation or comply with SANAS ISO 15189 standard.
f. The practice can participate in external audits, inter laboratory quality control schemes or subscribe to ISO accredited proficiency testing scheme providers to ensure good quality results.
g. The practice can apply to SANAS to train the staff on SANAS ISO 15189 standard. This will assist the laboratory in the implementation of the quality management system.

13. LABORATORY ACCREDITATION

It is a formal recognition of competence, by an authoritative third party. It is about Laboratory's competence in producing consistent and reliable results/measurements for a defined set of methods activities, providing means for customers to identify and select reliable testing, measurement services to meet their needs.

14. CONFORMITY ASSESSMENT TO ISO 15189

The Standard (ISO 15189) encompasses all the assessment criteria specified in the policy statement and as such should form the basis for accreditation of laboratories focuses on the patient outcome without downgrading the need for accuracy of measurements It emphasizes not only the quality of the measurement but of the total service of a medical laboratory (consultation, turn-around time, cost effectiveness etc.)

15. BUSINESS ADMINISTRATION

Ethical Guidelines are available on HPCSA website.

a. Naming of the practice – practice must reflect the name of the MT/MLS in whose name the practice is registered in. The naming of the practice is correctly reflected as per HPCSA ethical guidelines. The naming of your practice needs to state that it is a Medical Technology Pathology practice.

b. Scope of Profession – Laboratory tests must be performed and signed out by a registered, qualified MT/MLS within his/her scope of practice

c. Laboratory Request forms – Need to reflect correct name, practice number of practice. The request form should not contain profiles or "shopping lists" of tests

d. Results report – needs to reflect correct name, practice number of person accepting responsibility of report.

e. If test performed at a referral laboratory, the report needs to reflect this. Tests referred to laboratories outside scope of practice needs to reflect the referring laboratory on the report. / An addendum to the report must reflect that the result has been performed by a referring laboratory. This is an ethical guideline of the HPCSA.

f. Informed consent for certain laboratory tests

g. Specimen Collection

h. Indemnity Insurance - As per Section 46 of the National Health Act, every private health establishment must maintain insurance cover to indemnify a user for damages that he/she might suffer as a consequence of a wrongful act by any member of staff.

16. TEST REPERTOIRE, ICD 10 CODES AND TARIFFS

Medical Technologists/Medical Laboratory Scientists should be able to offer a large menu of tests depending on several requirements:

a. The Medical technologist or Scientist that performs the test must be practicing within the scope of their qualifications and HPCSA registration Qualified practitioners who must not practice out of scope

b. Available laboratory equipment

- Instrumentation must be present in the practice that can perform the tests that are performed in the laboratory
- The Practice must on request be able to show proof of purchasing the reagents and consumables required to perform the tests in the laboratory

i. Demand from the referring doctors. Whilst the use of educational material to referring doctors is encouraged in respect of new tests and new services the Medical technologist should be wary of crossing the divide in respect of building an increased demand for testing.

ii. Specialised tests not performed by the Laboratory should be referred to the nearest reference laboratory with whom the practice has an agreement to perform such tests.

iii. A formal written agreement with the reference laboratory is essential detailing the relationship between the referring practice and the reference laboratory

iv. Coding and Tariffs:

- The use of a four-digit code for the billing of tests is the current format for billing
- This code must be accompanied by the name of the test that was performed and is being billed for
- Where a specific code exists for a test it must be used
- Where a generic code is used the name of the test must be supplied
- Only tests that are requested can be billed. Medical aids may request confirmation of tests requested by referring Medical Practitioner .
- Where a Medical Practitioner requests a test to be added on to an order a record of that request must be kept and be made available should a funder require proof of the request

- Medical technologists are not allowed to have profiles of tests on their practice request notes. This is a reference to the original conditions under which the right of private practice was granted (no shopping lists of tests)
- Calculated results cannot be billed for under any circumstance
- Reflex testing is only allowed when confirmed with the referring Medical Practitioner.
- A record of that confirmation must be kept in case it needs to be audited.

16.1 REQUEST FORMS

a. The test requisition form allows laboratories to collect data accurately and includes data like age, gender, treating doctor, hospital, ward, contact numbers, address details of the guardian or parent, etc. and are designed to assist doctors in the clinical setting they find themselves. • ICD 10 codes and important clinical data are collected through this request form. Commonly used tests are grouped together in a logical format.

b. Pricing of tests – Under the original resolution, the Medical Technologist practice rate of 83% of the Specialist Pathologists was set. There is no current legislated rate at present however the differential generally exists between Medical Technology practices and Specialist pathology practices

- Many Medical Schemes have a scheme rate at which providers are paid at.
- Many funders have restrictions on the amounts of tests or limits for pathology in their benefit schedules
- It is the Medical Technologists' responsibility to inform themselves of these limits
- Medical Technology practices and Medical funders are free to negotiate tariffs

c. Consumables and collection materials

- Collection materials and consumables can only be billed in certain restricted areas
- Blood culture Bottles, Sweat Test consumables, Bleeding time consumables

d. ICD Codes - The use of ICD codes is increasing in need, importance and relevance. The following points must be borne in mind in respect of ICD10 codes

- ICD 10 codes are designed to give an international common ground, interpretation and understanding for the interpretation of the disease status. This is invaluable for funders of pathology tests.
- Avoid using ICD 10 codes such as Z1.07 and Z76.9 because they only indicate that a laboratory test was conducted but provides no value.
- Follow the link below for ICD 10 codes.
  https://www.medicalschemes.com/medical schemes pmb/ICD-10 codes.htm
- Where ICD 10 codes that are relevant to the laboratory generated results are available, they must be supplied on the account generated.
- All medical aids or bodies representing them have the right to request information regarding testing / referrals or may request to view referral forms if any form of audit or query is been held regarding charges levied at a particular medical aid scheme.