

# **SUBMISSION BY PATHCARE ON BILL 24-2011 ON THE ESTABLISHMENT OF AN OFFICE OF HEALTH STANDARDS COMPLIANCE IN TERMS OF THE NATIONAL HEALTH ACT OF 2003**

**9 MARCH 2012**

## **1. WHO WE ARE**

**PathCare** (Drs Dietrich Voigt Mia and Partners) is a significant South African healthcare entity that employs over 2500 people and provides laboratory services to over 3.2 million South Africans per year. Further details regarding PathCare can be found in **Annexure A**.

## **2. QUALITY ASSURANCE PRACTICES – EXPERIENCES OF PATHCARE LABORATORIES**

**PathCare** has long recognized the fundamental requirement for quality in the pathology laboratory environment and became the first laboratory in Africa to be accredited to ISO standards by SANAS in 2000. PathCare currently has 64 laboratories accredited in South Africa and Namibia. PathCare Kenya was the first medical laboratory in East Africa to be accredited to ISO by SANAS in 2004. PathCare Nigeria was the first medical laboratory in West Africa to be accredited to ISO by SANAS in 2005. The PathCare Quality Assurance division assisted a partner lab (Medlab Ghana) to be the first accredited in Ghana in 2006.

We have more than 10 years' experience in implementing an integrated Quality Management System. Further details regarding PathCare's experience in Quality Assurance and Quality Management can be found in **Annexure B**.

## **3. COMMENTS ON BILL 24-2011**

PathCare welcomes the establishment of the Office of Health Standards Compliance (OHSC) as a mechanism to ensure the quality of service is never compromised and services are used effectively and safely.

No other discipline in healthcare provision has a better track-record than Laboratory Medicine in consistently measuring and monitoring and improving quality. We recommend that, insofar as laboratory medicine is concerned, standards are aligned and that accreditation, and enforcement of the standards is harmonised between, for example, the system envisaged by the proposed medical device licensing regulation, the control of Hazardous Substances system and ISO accreditation, as well as the licensing system referred to in the HRH Strategy, 2011 (and the possible implementation of the Certificate of Need in terms of section 36 of the National Health Act).

We make our comments below under the following thematic headings:

### **3.1 Independence of the OHSC**

PathCare notes that the OHSC is intended to be independent. It is minuted by the Parliamentary Portfolio Committee (PMG) on 14 February 2012 that "the Office of Health Standards Compliance would perform independent oversight on healthcare, with or without reference to the Minister and

yet would report to the Minister.” As the Minister of Health is responsible for the health sector, which is to be accredited and inspected by this body, PathCare does not believe that the OHSC would be truly independent. PathCare does not have any concerns relating to the OHSC advising the Minister from time to time, however does believe that conflicts could arise in terms of the Minister setting the standards that would apply to the health sector of which s/he is the head.

PathCare therefore proposes that the wording as found in clauses 77, 78, and 79(1)(a) and (f) be more explicit in terms of the intention for independence (the word “independence” are absent from these two clauses that frames the nature and overarching objectives of the OHSC).

PathCare also notes from the discussions at the Portfolio Committee of Health in February on this matter, that it is intended for the OHSC (as an independent public entity) to retain its fees as part of being independent. However, the wording in the Medicine Act of 1965 is identical to that proposed in Bill 24 – 2011, and the MCC is not able to retain its funding at source. It is proposed that the retention of funding and fees at source be worded differently, in order to ensure that this objective is actually achieved.

### **3.2 Interaction and integration of other pieces of legislation**

PathCare strongly advises that the way in which the OHSC is organised through the amendment to the National Health Act should prevent duplication of efforts and resources, as it would erode the very important NHI principles of efficiency and cost-effectiveness.

#### **3.2.1 Dealing with general overlaps i.t.o. health- and health professional legislation**

Clause 79(2)(e) recognizes the potential for conflicting legislative mandates, but merely suggests that the OHSC should negotiate cooperative agreements to harmonise jurisdictions. Where laws overlap or conflict, the executive cannot agree to ignore or smooth over such conflicts, and any agreement of one body to not exercise its legislative mandate in favour of another, is likely to attract unnecessary legal challenges. In PathCare’s view this would detract from the important work of the OHSC and erode the mandate of the OHSC.

PathCare proposes that the Portfolio Committee request an analysis of such potentially overlapping and/or conflicting laws, and work in clear provisions on the delineation of mandates. To better manage this, PathCare proposes that the following wording could be included under clause 79(2)(e):

*“Where another entity or body has, in terms of an empowering Act of Parliament, accredited, registered or licensed a health establishment and/or the professionals and/or products therein, such accreditation, registration and/or licensing shall be accepted by the OHSC as sufficient proof of compliance with the specific standards thus accredited, registered or licensed”.*

This will prevent circumstances where, for example, the Health Professions Council of SA (HPCSA) permits, for instance a laboratory technician to undertake certain work within a certain context, whereas a standard set by the OHSC may demand a different procedure or standard to be followed. All professional statutory bodies have inspectorates and complaints mechanisms that relates to the professional standards of the work of practices and individuals for which a clear delineation of legislative mandates is required. Complaints relating to the professional (including (un)ethical) conduct of persons registered at bodies such as the Nursing Council, HPCSA, Pharmacy Council, etc. should be directed to such entities.

### 3.2.2 Specific standards applicable to pathology<sup>i1</sup>

The appropriate accreditation system for pathology laboratories, as established by the Standards Act, is SANAS accreditation. This is an international accreditation by an independent body. Pathology operations in Namibia, Kenya and Nigeria are also accredited to these strict standards. SANAS uses the international standard ISO 15189 as the basis for their assessment of a medical laboratory's compliance with an international standard. The primary function of ISO (International Organisation for Standardisation) is to establish the same standard throughout the world. This provides the assurance that the result is reliable to a standard equal to the best in the world. Laboratory accreditation provides formal recognition to competent laboratories, thus provides a ready means for customers to access reliable testing services.

This accreditation process involves a thorough evaluation of all the elements of a laboratory that contribute to the production of accurate and reliable test data. Requiring certification by the OHSC in terms of additional norms and standards for pathology services (which fall under the definition of "health establishment" in the Act) is a duplication of services already rendered by SANAS, and is therefore not necessary. Imposing the current Core Standards (referred to in the Parliamentary briefing) in addition to the SANAS accreditation would not be fit for purpose, as the nature of the services rendered in laboratories such as PathCare's differ from that delivered in other specialist practices and from that delivered in clinics and hospitals.

It also adds an additional cost to the certification process, which ultimately will lead to an increase in overall health care services to the public. The fees and costs (ensuring readiness for inspections, etc.) associated with SANAS accreditation and certification are already significant. The annual costs of accrediting and/or retaining accreditation per laboratory range between R15,000 and R50,000 per annum; PathCare's annual costs to maintain accreditation of its laboratories amount to R700 000.

### 3.3 Certificate of Need (CON)

PathCare deducts from the wording in the proposed amendment to section 36, that the OHSC certification would be relevant for a health establishment's CON, and that the OHSC will also enforce the various criteria found in section 36 on which a CON would be awarded or denied. The CON has been a highly contentious issue, and it urges the Portfolio Committee to interrogate the submissions made by healthcare professionals on this matter prior to the adoption of the Act. Furthermore, regulations would have to be promulgated to make the details around the CON known, so that healthcare practices can evaluate the impact thereof on its businesses and business models. Without such details, assessing the implications within the context of the Amendment Bill is difficult.

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<sup>1</sup>In compiling this section PathCare was assisted by the National Manager of QA Division who is an expert in this field, **Ms Janette Wassing** (ND: Medical Technology (Chemical Pathology); ND: Medical Technology (Clinical Pathology); Registration with Health Professions Council of South Africa in the Category Chemical Pathology and Clinical Pathology; Member of Society of Medical Technologists in South Africa; Secretary and member of Scientific Advisory Committee of the Cape Town University of Technology in the category Chemical Pathology; Member of sub-committee of the international US-based Clinical and Laboratory Standards Institute (CLSI) that developed POCT08-P: Quality Practices in Non-instrumented Near-Patient Testing: An Instructional Manual and Resources for Health Care Workers; Chair of the SABS/ TC 212 Committee, responsible for writing and reviewing, amongst others, the ISO 15189 standard; Member of a CLSI sub-committee that is in the process of developing GP39-P: Quality Management System: Laboratory Internal Audit Program; Registered Technical and Lead Assessor with SANAS.

Moreover, section 47 refers to standards published by the Minister after consultation with the National Health Council. These standards will, however not be promulgated under the chapter governing the OHSC, and will not, as is currently proposed, be published on the advice of the OHSC, but will nonetheless be enforced by the OHSC.

It is not clear to PathCare why there would be two sets of quality provisions and standards applicable to health establishments, one in terms of Chapter 6 of the Act, and another set in terms of the new Chapter 10.

### **3.4 Current set of Core Standards**

During the meeting with the Portfolio Committee the Department of Health referred to the set of Core Standards that are currently being used, and although not law yet, would undoubtedly become the basis for accreditation in the future.

PathCare find the applicability of these standards to its laboratories (“health establishments”) inappropriate, as these are not “fit for purpose”. These standards are designed for the assessment of health establishments that are providing clinical services. Pathology laboratories provide healthcare to the patient indirectly, as it is the clinician who requests the laboratory test and communicates the result and implication to the patient’s management for the patient.

Of the 6 Core Standards, *Cleanliness, Safety & Security, Infection Control* and *Long Queues and waiting times* (which can be equated to Turnaround Time in the laboratory setting) are all assessed rigorously, robustly and in great detail during SANAS audits for accreditation under ISO 15189. Core standard of *Managing Drug Stock* is not applicable to the laboratory setting at all.

Of concern to PathCare is that the core standards are predominantly input and efficiency indicators with very few output and outcome indicators. It is therefore unlikely to impact effectiveness of care and health outcomes (as per objectives such as those set by the *Millennium Development Goals*, and the principles espoused in the *Policy Paper: National Health Insurance in South Africa*). Such output and outcome indicators are essential components of “quality healthcare”.

### **3.5 Issuing of standards**

PathCare would also urge, as is mentioned in the NHI Green Paper, that the OHSC benchmarks its standards internationally. The Bill is not clear who will actually write the standards.

PathCare proposes that the clauses in the Bill where standard-setting are referred to, be refined to include criteria for- and processes in terms of which such standards are being set. This is, in PathCare’s view, important to secure the independence, general acceptability and alignment of standards being set for enforcement. Criteria for standards would include, amongst others:

- Alignment, insofar as is possible, with international standards;
- Recognition of existing standards and certification, registration and licensing in terms of such standards;
- Standards should be applicable and relevant to the nature and purpose of the specific type of health establishment.

As far as process is concerned, PathCare proposes a system whereby expert technical committees advise on the possible standards to be adopted, draft standards are published for comment, and finalization post consideration of comment received. Based on PathCare’s experience with SANAS

accreditation, deadlines for facilities being audited for certification are very strictly applied. Given that the risk and penalties for non-compliance are not insignificant, it would be important that responsiveness of OHSC should also be specified.

### 3.6 Other issues

- PathCare noted the query from Parliamentary Portfolio Committee as to “how private sector prices (fees / tariffs) would be regulated”. Instead of responding that this was outside of the ambit of OHSC, the Honourable Deputy Minister answered that “It was necessary to regulate”. PathCare would also urge the Portfolio Committee to, should this be a matter of concern, call upon stakeholders to make submissions to it on these matters, based on clear proposals on regulatory models that the Department of Health has in mind.
- Clause 27(2) gives the OHSC the right to request “any” information. PathCare submits that this is too wide and would violate, amongst others, protections afforded to personal information (i.t.o. the National Health Act and ethical rules), commercial information (i.t.o. the Promotion of Access to Information Act), etc. Clause 82, i.e. “*Health officer or inspector (with assistant) may enter to inspect, question, examine documents, **take samples or photographs** (within provisions of respect for property, privacy)*” further provides unclear delineation of these powers, and could be challenged on constitutional grounds, as the nature of the “respect for property and privacy” is not clearly outlined.

A clear provision protecting the confidentiality of all information, data etc. that forms part of an inspection and/or accreditation must be inserted in the Bill.

Based on PathCare’s experience in this field, it is imperative that inspectors be defined in terms of experience, qualification training, independence etc.

## 4. CONCLUSION

PathCare is more than willing to assist with the legislative processes currently unfolding, and also offers its assistance to the Portfolio Committee, Department and OHSC post these processes. It wishes to reiterate its unequivocal support for all steps aimed at ensuring quality of care and better health outcomes for all South Africans.

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## ANNEXURE A

- **PathCare** (Drs Dietrich Voigt Mia and Partners) is a partnership of pathologists and technologists that provides medical laboratory investigations (predominantly blood tests) for doctors and other healthcare workers in South Africa and Namibia.
- **PathCare** has over 150 referral sites where patients can be attended to by qualified phlebotomists and nursing staff. Sixty three of these sites include a laboratory either in hospital or near hospital to be able to provide results as rapidly as possible for urgent matters.
- We have 80 pathologists in all disciplines of pathology and over 2,500 staff including nursing staff, medical technologists, technicians, phlebotomists, laboratory assistants, couriers, etc.
- **PathCare** covers the Western Cape, Northern Cape, North West, Free State Eastern Cape, and Gauteng in South Africa.
- **PathCare** collects specimens from hospitals and doctors' rooms including outlying areas and smaller towns in all these provinces.
- We are a proudly South African business, and extend our focus to Africa with operations in Nigeria, Kenya, Lesotho, and Namibia.
- **PathCare** was the first South African medical laboratory to receive accreditation through the South African National Accreditation System (SANAS).
- Specimens are analysed in laboratories that adhere to ISO guidelines and the results are communicated to doctors by multiple means, including post, and electronically through a **PathCare** secure internet system.
- Through the healthcare worker, **PathCare** provides valuable investigative services that ultimately benefit the patient.
- **PathCare** has developed strong relationships with allied professionals, including the National Health Laboratory Service, and continues to be committed to working with other service providers to improve delivery and accessibility in a cost effective way.
- Private medical schemes consider **PathCare** to be the most cost effective pathology laboratory in the country.
- **PathCare** is committed to skills development and its laboratories are accredited training institutions. Over the past 5 years, the **PathCare** Training Academy has trained 84 Medical Technologists, 148 Medical Technicians, 93 Phlebotomy Technicians, and 92 Laboratory Assistants. This represents 9% of Medical Technologists; 13% of Medical Technicians; 30% of Phlebotomy Technicians; and 42% of Laboratory Assistants in South Africa. Short courses specific to the needs of employees are presented regularly, with over 17,000 courses presented over the past 5 years (thus every member of staff has had access to an average of 1.5 short courses per annum.)

## **Annexure B**

### **QUALITY ASSURANCE PRACTICES – EXPERIENCES OF LABORATORIES**

The increasing awareness of the costly personal and economic impact of medical errors on patient safety has focused a spotlight on quality management in healthcare services. In the present environment of limited resources, quality cannot be taken for granted by those who fund, receive, and provide laboratory services. Our historical perspective of quality control and quality assurance must be superseded by a more global view of internationally accepted quality activities applied to a laboratory's scope of work.

An integrated Quality Management System provides an opportunity to deliver consistent, high-quality, and cost-effective laboratory services.

Although some laboratories are working successfully at the level of a Quality Management System, in much of the world, many laboratories are operating at or below the stage of quality assurance. The need to upgrade to a Quality Management System approach has become evident from worldwide reports that describe medical errors in present-day health care systems and from reports of the cost of both good and poor quality on laboratory operations. The best contribution a laboratory can make to reducing errors that can or may cause harm is to understand and document processes, train staff to competency in following those processes, identify problematic processes, and improve processes where problems exist.

The foundation of a Quality Management System provides a platform for continuous improvement and further transition up the quality hierarchy. With an integrated Quality Management System in place, the following outcomes can be greatly enhanced:

- Ability to reduce or eliminate error
- Meeting customer expectations
- Potential for successful governmental and accreditation assessments
- Sustainable attainment of quality objectives

Accreditation to a global standard, such as ISO 15189 provides a platform for recognizing quality and competency in laboratories.

### **PATHCARE ASSISTANCE WITH QUALITY ASSURANCE AND QUALITY OF CARE IN THE NHI**

#### **1. Training in Quality Management**

**PathCare** was the first laboratory in Africa to be accredited to ISO standards by SANAS in 2000. We have more than 10 years' experience in implementing an integrated Quality Management System, and can offer training in this regard. SANAS (The South African National Accreditation System) is currently the only accreditation body in South Africa responsible for carrying out accreditations in respect of conformity assessment, calibration and good laboratory practice. Many **PathCare** staff members are certified SANAS assessors, and as such could provide valuable input into the structure of accreditation/ conformity assessments in South Africa. Furthermore, **PathCare** has experience in international quality management organizations and committees, such as ISO and CLSI, and thus has much to offer in quality management expertise.

Currently **PathCare** runs several courses in quality assurance and quality management; such as Quality Control, Method Validation, Total Quality Management and Internal Auditing Techniques. We can offer training at any level of Quality Assurance and Management, from basic primary health facilities to advanced healthcare settings.

**2. Performing GAP analyses to benchmark level of quality in health care facilities**

**PathCare** has vast experience in undertaking GAP analyses and implementing effective laboratory and quality models in laboratories in South Africa, Namibia, Kenya, Nigeria, Ghana, Ethiopia and Zimbabwe. We understand the challenges that different countries undergo in terms of implementing quality laboratory services, and can assist with performing GAP analyses, training and other benchmarking activities in healthcare facilities in resource-constrained environments.

**3. Assistance with delivery of an integrated Point of Care infrastructure in South Africa to assist with primary health care delivery**

One of the strong focuses in the NHI Green Paper is the need for quality services at the Primary Health Care level. As a long standing accredited facility, **PathCare** has the expertise to assist with building an effective laboratory service model at Primary Health Care level. The best option at this level would include Point-of-Care (POC) instrumentation. **PathCare** has years of experience with validating and selecting fit-for-purpose POC instrumentation, as well as links with world standards organizations, such as ISO and CLSI, and can assist the Department in this regard. Furthermore, POC services have different working models versus main stream laboratory instrumentation, and training and effective roll out of this service is crucial, which **PathCare** is once again able to offer its assistance.

**4. Assistance with method harmonization in the South African healthcare framework**

**PathCare** has vast experience in the field of validation and harmonization of methods in clinical laboratories, to ensure that all patients receive a standardized, world class laboratory service in South Africa.

We can assist and collaborate with the drafting of technical and quality management guidelines, to provide a standardized level of quality healthcare services in SA.