Comments on the
Draft National Quality Standards for the Health Laboratory

April 2011
1.0 Introduction

The Consumer Council of Fiji believes that the establishment of national quality standards for health laboratories in Fiji is long overdue particularly at a time when there is growth in private health care and when more consumers are opting for private health, medical and dental services which include private sector labs. It also comes at a time when public health services are under pressure from population growth and migration of experienced and qualified practitioners to so-called greener pastures overseas. Historically public confidence in public health and medical services have been low, while the development of private, pay-for-service health care has not really improved the situation as shown by consumer complaints against private practitioners or health centres. The Fiji Government in late 1990s promoted the growth and development of private sector health services and also encouraged consumers who can afford, to seek the services of private practitioners and thus relieve pressure on public health infrastructure. This was in line with the Government policy trend of public-private partnership in development. However, the lack of proper standards and redress is leaving many consumers vulnerable and at risk.

1.1 Role of Consumer Council of Fiji

The Council has statutory obligations under the Consumer Council of Fiji Act (Cap 235) to “to do all such acts and things which it may consider necessary or expedient to ensure that the interests of consumers of goods and services are promoted and protected.” The Council is also obliged to advise and make recommendations to the Minister responsible for consumer affairs in Fiji or any other Minister on issues affecting the interests of consumers. This work extends to providing advice and making submissions to policymaking bodies, government ministries, private sector or industry groups and international agencies. The Council is a key stakeholder in the formulation of policies, legislations and standards in the country.

1.2 Consumer Council of Fiji and Health Issues

The Council believes that every consumer should have accessible, affordable and reliable health services. In recent years, the Council has increasingly become concerned with the quality of health services particularly with the liberalisation of this sector and the trend towards private health care. The Council supports the policy objectives and targets set by the World Health Organisation (WHO) during the 51st World Health Assembly – “Health for All in the 21st Century”. On health and medical matters, the Council, in its strategic plan has pledged to:

- promote patients’ rights and redress;
- raise awareness on misleading advertisements and door to door sale of alternative medicines such as herbal medicines, therapeutic treatments etc;
- lobby for implementation of the National Drug Policy;
- advocate for increased consumer access to safe and affordable pharmaceutical products;
monitor anti-competitive market practice in the pharmaceutical sector and auxiliary health services; and

ensure necessary reforms take place in public and private medical and dental practices for efficient, accessible, affordable and safe delivery of health services.

The Council’s participation in this consultative exercise on the draft standards for health laboratories is thus necessary and extremely appropriate.

1.3 **Consumer access to laboratory services**

The Council understands that consumer access to laboratory services is most often through a third party, i.e. their general practitioner, specialist or local hospital/clinic. Thus in most instances they are not directly involved in acquiring the services of the labs. General practitioners, specialists and hospitals often use their own in-house labs or refer tests to other labs that may have general services or specialise in particular health/medical fields. Consumers often have to rely on what is provided by their GP or hospital and may not have direct say in which laboratory is involved. The assessment of services of laboratories thus is done mostly by other parties rather than the consumer who only receives the final lab results from his/her doctor. It is therefore crucial for any standards to ensure there is a high level of transparency and accountability provided to the consumer in this process.

1.4 **Standards**

The Council is a strong advocate for standards on goods and services. International rules and standards have major impact on safe design, performance and fit for purpose of products and services, and hence provide vital safeguards and protection for consumers. Standards should take into account consumer concerns and grievances of the product and services which consumers use in their daily lives. Standards accreditation to a recognised international standards-making body such as ISO is one important response to consumer concerns over quality and safety of goods and services. In this regard the Council regularly lobbies the Department of Trade Measurement and Standards to develop and implement standards. The Council is also a member of the Trade Standard and Advisory Council. We have identified standards to be one of the weak areas of Fiji’s economy and recognise that the gap in standards is having negative implications for consumer rights to quality and safety in the marketplace.
2.0 COMMENTS ON THE DRAFT STANDARDS

The Consumer Council strongly support this initiative and believes that the establishment of the standards will improve consumer confidence in the health sector as a whole. The Council is happy that the standards are aligned to ISO15189 and WHO Regional Laboratory Standards. The comments below are on particular aspects of the draft paper where we feel our views are important and which we hope will strengthen the draft further. We must emphasis at first that our key recommendation is on the establishment of proper consumer redress mechanisms for health laboratories.

2.1 Scope and Objectives

2.1.1 The Council fully supports the intentions outlined in paragraph four, Part 0.1 General: *The purpose of establishing laboratory quality standards is to ensure accuracy of test results, increase the confidence of patients, clinicians and communities in the value of laboratory testing and informed patient management.* We hope that the national standards will lift current lab practices to be on par with international best practice and ensure patients’ rights to quality and affordable health services are met.

2.1.2 Paragraph 1.1 Scope and Objectives – The Council feels that the issue of consumer redress should also be included. Consumers who access health laboratories either directly either through a third party (i.e. general practitioner, hospital etc) need some form of redress mechanisms where complaints against errors or quality of services can be taken care of. While complaints procedures is referred to briefly in Part 4.0 Customer Service & Resolution of Complaints, the Council feels that this item should be highlighted prominently in the Scope and Objectives. Also Part 4.0 should be expanded to include specific customer redress mechanisms, for example timeline for resolution of complaints, complaints registration, identify key personnel responsible for complaints, etc.

2.2 Quality Management System (QMS)

2.2.1 The Council supports the outlined QMS practices. We recommend if manuals and other appropriate documentation be made available to all stakeholders and not only those agencies involved in monitoring and appraisals.

2.3 Human Resource (Personnel)

2.3.1 We recommend that a minimum qualification is clearly stipulated with experience. Need for continuous education and training for lab personnel be highlighted and made as requirement. Regular training should also involve understanding customer needs and quality customer care. Lab personnel may be highly qualified and experience in their field, however many may not have had training in customer services and other relevant areas.
2.3.2 We recommend that all laboratory technicians or personnel be part of a professional industry group, for example a National Association of Health & Medical Laboratory Technicians. This would help in self-monitoring and strengthening of lab technician practice standards.

2.4 Accommodation & Environmental Conditions

2.4.1 The Council notes that references are made to appropriate biosafety environment and facilities for laboratories, which is good. However, there is no mention of any of the regulatory or monitoring agencies responsible to ensure that standards are maintained. For example agencies like the biosafety department, Department of Environment, Central Board of Health, municipal councils, etc. This area could be strengthened by identifying these key agencies and how laboratories should be aware of the laws and regulations relating to the environment and public health.

2.4.2 Disposal of infectious waste (Paragraph 4.4.7) – There should be references to the Department of Environment’s policies on solid waste management and compliance with relevant regulations under the department.

2.5 Laboratory Equipment

We recommend that this area (Part 4.6) be further strengthened by assurances that all equipment used shall be those that comply with international standards. Most lab equipment are imported and it is important that Fiji health labs are not used as dumping ground for substandard equipment. Also of concern is whether the equipment are regularly serviced to ensure they work well and give accurate results. So a checklist is important along with a register that records maintenance and service schedule and details.

2.6 Information Management

This is important consumer concern as the Council has noted the laxity in record and information management in the health sector generally, particularly amongst general practitioners. The Council is happy that the draft has standards on record keeping. The importance of proper documentation is important especially when consumer complaints arise.

2.7 Customer Service & Resolution of Complaints

2.7.1 As discussed in 2.1.2 above, the Council recommends that this area be expanded and strengthened. The standards are geared toward increasing the confidence of patients and ensuring that services rendered equate with the applicable fees and charges and the result is correct. The Council stresses that consumer redress is a very important aspect of service delivery in any business or government service. Also medical laboratories are a crucial aspect of patient management as a patient’s health and life are at stake here. A proper consumer complaints or redress system must be established.
not only to protect the rights of patients (or consumers of medical lab services), but also to build a high level of confidence in the system.

2.7.2 Laboratories should establish their in-house consumer complaints or redress system that covers:

- procedures for receiving or registration of complaints;
- a complaints form for customers, to ensure proper record keeping
- a standard time period for resolution of complaints;
- identifying a key personnel(s) who will also be responsible complaints management (same personnel can be those in customer service/front desk, and the lab technicians); etc

Laboratories can seek advice on complaints management from consumer protection agencies such as the Consumer Council of Fiji, Commerce Commission, Ministry of Health Food Unit, etc.

3.0 CONCLUSION

The Consumer Council welcomes and fully supports the establishment of National Quality Standards for the Health Laboratory. The standards will not only improve services, but also enhance consumer confidence in the local health sector as a whole. We hope that our key recommendation of establishing a proper consumer redress mechanisms will be considered. The Council hopes that the establishment of these standards will have a trickle effect on other health sectors in Fiji, and also in other government services or private sector businesses.