EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973
SECTION 23DNA

HEALTH INSURANCE (ACCREDITED PATHOLOGY LABORATORIES – APPROVAL) PRINCIPLES 2007

Section 23DNA of the *Health Insurance Act 1973* (the Act) provides for the Minister to determine principles to be applied by the Minister in exercising powers under section 23DN of the Act to approve in principle, or not to approve, premises as an accredited pathology laboratory.

Medicare benefits, apart from some basic tests conducted by treating medical practitioners on their own patients, are not payable in respect of pathology services unless they are rendered in an accredited pathology laboratory. The determined accreditation principles operate to ensure minimum acceptable standards in pathology laboratories. The determined principles also make reference to National Pathology Accreditation Advisory Council (NPAAC) documents which are standards, guidelines and other assessment aids that must be taken into account during the accreditation process. The Medicare Australia administers the accreditation process.

NPAAC has endorsed the following new and revised documents, which are now included in Schedule 1 of the Principles:

1. Requirements for the Estimation of Measurement Uncertainty (New document)
All types of measurements have some inaccuracies and therefore measurement results can only be estimates of the quantities being measured. This new document provides guidance for the degree of variation in measurements that is acceptable. It provides a diverse range of examples for the different disciplines of pathology to consider when estimating measurement uncertainty. Currently, medical laboratories use quality control management processes to monitor the whole of procedure performance and generate quality data to directly estimate their combined measurement uncertainties. This document will help reduce the inaccuracies in measurement results.

2. Requirements for Pathology Laboratories (Revised document)
This is the primary NPAAC document that determines the minimum standards acceptable for good pathology laboratory practice in Australia. It addresses a variety of issues such as: laboratory ethics, quality systems, facilities, staffing, analytical phases of the pathology process, audit and assessment. Other NPAAC documents go into further detail on most of these issues.

3. Requirements for In-house In Vitro Diagnostic Devices (Revised document)
An IVD is a device (or in some cases a kit) that is used to test a sample or a specimen from a patient. They are classified as therapeutic goods and are subject to regulation under *The Therapeutic Goods Act 1989*

This document has been revised in conjunction with the Therapeutic Goods Administration (TGA) to warrant conformity with its Essential principles for quality, safety and performance and to ensure IVDs are manufactured to the same standard and safety as those that are commercially available.

4. Requirements for Quality Management in Medical Laboratories (Revised document)
This document aims to help laboratories interpret the application of the Australian Standard AS 4633:2004 – *Particular requirements for quality and competence* and the International Organisation for Standardisation (ISO) standard ISO 15189:2003 *Medical laboratories – Particular requirements for quality and competence.*

The Office of Regulation Review advised that a Regulation Impact Statement (RIS) was not required for this change.

These documents were revised with extensive input from the pathology profession. As part of the established NPAAC public consultation process all documents prepared by NPAAC are circulated to all laboratories within Australia, NPAAC members, Jurisdictional members and members of industry.

This amendment also makes a number of minor drafting corrections to the Principles.

The revised Principles come into effect on 1 July 2007.