EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973
SECTION 23DNA

HEALTH INSURANCE (ACCREDITED PATHOLOGY LABORATORIES – APPROVAL) PRINCIPLES 2006

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 (NCAAP) documents which are standards, guidelines and other assessment aids that must be taken into account during the accreditation process. The Health Insurance commission administers the accreditation process.

NPAAC has revised two documents to provide updated and current guidance for laboratories. The revised documents are: *Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection and Analysis and Guidelines for Approved Pathology Collection Centres*. These documents were revised with extensive input from the pathology profession.

The *Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection and Analysis* provides consensus standards and guidelines. It is directed at laboratories that are either using nucleic acid detection techniques in medical diagnosis, or intending to establish a testing program using these techniques. The document also informs accreditation authorities such as the National Association of Testing Authorities, Australia, so that laboratories using nucleic acid detection techniques may be assessed for compliance.

The *Guidelines for Approved Pathology Collection Centres* provides guidelines for the premises and operations of Approved Pathology Collection Centres (APCCs). The Guidelines list the minimum requirements that apply to collection facilities utilised in the collection of samples for Medicare-billed testing in Accredited Pathology Laboratories (APLs) or Medicare-equivalent episodes such as those patients of the Department of Veterans Affairs.

The guidelines may also apply to pathology laboratories seeking accreditation outside of the Medicare benefits arrangements.

The Office of Regulation Review advised that a Regulation Impact Statement (RIS) was not required for either of these reviews.

The commencement date for the determination of the *Laboratory Accreditation Standards and Guidelines for Nucleic Acid Detection and Analysis and Guidelines for Approved Pathology Collection Centres* is 1 August 2006.