

## EXPLANATORY STATEMENT

### HEALTH INSURANCE ACT 1973

#### *Health Insurance (Approved Pathology Undertakings) Approval 2017*

Subsection 23DB(1) of the *Health Insurance Act 1973* ('the Act') provides for the Minister to approve, by legislative instrument, forms of undertakings to be given by persons who wish to become approved pathology practitioners or approved pathology authorities. The current forms of undertaking are approved in the *Health Insurance (Approved Pathology Undertakings) Approval 2002* (the Undertakings Instrument 2002).

With the exception of some basic tests conducted by some medical practitioners within their own medical practice, Medicare benefits for pathology services are only payable when they are rendered by or on behalf of an approved pathology practitioner, in an accredited pathology laboratory operated by an approved pathology authority. One of the requirements of becoming an approved pathology practitioner, or an approved pathology authority, as appropriate, is that the person has given an undertaking in the approved form and the Minister has accepted that undertaking.

The Undertakings Instrument 2002 is due to be repealed on 1 October 2017 as a result of the sunset provisions in the *Legislation Act 2003*. The *Health Insurance (Approved Pathology Undertakings) Approval 2017* (the Undertakings Instrument 2017) revokes the Undertakings Instrument 2002 and approves new forms of undertakings to ensure that pathologists and pathology providers can continue to give undertakings which will allow them to become approved pathology providers and approved pathology authorities for the purposes of the Medicare scheme.

The approved forms of undertaking in the Undertakings Instrument 2017 set out obligations on approved pathology practitioners and approved pathology providers that ensure they are accountable for pathology services that are rendered by or on their behalf in an accredited pathology laboratory and with respect to their eligibility for Medicare rebates for pathology services. The overarching objective of the approved forms of undertaking is to ensure patient safety in the provision of pathology services.

The Undertakings Instrument 2017 is largely consistent with the Undertakings Instrument 2002, however it includes:

- changes to modernise drafting in line with current drafting standards;
- updates to references to positions within the Department of Human Services and the Department of Health, which share responsibility for accepting undertakings given by approved pathology practitioners and approved pathology authorities;
- updates to legislative references;
- other minor amendments that assure consistency with other legislation regulating the provision of pathology services for the purposes of Medicare.

In accordance with section 14 of *Legislation Act 2003*, the Undertaking Instrument 2017 incorporates other legislation as in force from time to time. Other documents are incorporated as in force at the time this legislative instrument takes effect.

Unless otherwise stated, all references to legislation in the legislative instrument are reference to that legislation as in force from time to time.

Details of the legislative instrument are set out in Attachment A.

## **Consultation**

The Department of Health has consulted with the Department of Human Services on the making of this instrument.

The Undertakings Instrument 2017 is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Undertakings Instrument 2017 commences on the day after it is registered.

**Details of the *Health Insurance (Approved Pathology Undertakings) Approval 2017***

**1. Name of legislative instrument**

Section 1 provides that the title of the instrument is the *Health Insurance (Approved Pathology Undertakings) Approval 2017*.

**2. Commencement**

Section 2 provides for the legislative instrument to commence the day after the instrument is registered on the Federal Register of Legislation.

**3. Authority**

Section 3 provides the authority for the legislative instrument under subsection 23DB(1) of the *Health Insurance Act 1973* (the Act).

**4. Definitions**

Section 4 provides that words in this legislative instrument have, unless otherwise defined, the same meaning as in the Act.

**5. Revocations**

Section 5 revokes all previous approvals made under subsection 23DB(1) of the Act..

**6. Approval of forms of undertaking**

Section 6 provides the approved forms of undertakings to be given by a person who wishes to become an Approved Pathology Practitioner (APP) or Approved Pathology Authority (APA).

**Schedule 1 Approved Pathology Practitioner Undertaking**

**Part 1 - Undertaking**

Schedule 1 deals with the form of undertaking to be given by a person wishing to become an APP.

This section sets out the definitions of terms used in the legislative instrument. Subsection 1(2) provides that a reference in the undertaking to writing, documents and records includes in an electronic form, where recorded and submitted in accordance with the *Notice of Information Technology (IT) Requirements under the Electronic Transactions Act 1999 for Public Key Technology (PKI)*, dated 1 October 2009 and as in force on that date. A copy of the notice is available free of charge at:

<https://www.humanservices.gov.au/organisations/health-professionals/services/medicare/public-key-infrastructure>.

The remainder of Part 1 specifies the responsibilities and standards the APP will undertake to meet in rendering any medicare eligible pathology services. . This Part requires the person completing the undertaking to acknowledge that they will personally supervise, and take responsibility for any person who renders services pathology on their behalf.

## **Part 2 – Legislation**

Part 2 lists the legislation that the person undertakes to comply with under section 2 of Part 1 of Schedule 1.

## **Part 3 – Items an APP may provide requesting practitioners**

Section 11 of Part 1 of Schedule 1 requires a person to undertake not to accept a request for services where any benefit or incentive, other than an item set out in Part 3, has been directly or indirectly offered or supplied to the requesting practitioner by the APA who employs or engages the APP. Part 3 outlines the items for the purposes of section 11. A note to Part 3 provides that these are generally single use items employed in the collection of pathology specimens. The list of items may be updated from time to time, through amendment to this instrument, in consultation with the Royal College of Pathologists of Australasia.

## **Part 4 – Laboratory Services**

Part 4 is relevant for subsection 3(4) of Part 1 of Schedule 1, which removes some of the requirements for personal supervision of the provision of pathology services by an APP where a laboratory is limited to the services (and associated equipment for those services) as specified in Part 4. The list of services in this Part may be updated from time to time, through amendment to this instrument, in consultation with the Royal College of Pathologists of Australasia.

## **Part 5 – Execution of undertaking**

Part 5 sets out the form of the execution of an undertaking by a person who wishes to become an APP.

## **Schedule 2 – Approved Pathology Authority Undertaking**

### **Part 1 – Undertaking**

Schedule 2 deals with the undertakings to be given by a person wishing to become an APA.

Section 1 of Part 1 sets out the definitions of terms used. Subsection 1(2) provides that a reference in the undertaking to writing, documents and records includes in an electronic form, where recorded and submitted in accordance with the *Notice of Information Technology (IT) Requirements under the Electronic Transactions Act 1999 for Public Key Technology (PKI)*, dated 1 October 2009 and as in force on that date. A copy of the notice is available free of charge at: <https://www.humanservices.gov.au/organisations/health-professionals/services/medicare/public-key-infrastructure>

The remainder of Part 1 specifies the responsibilities and standards the APA will undertake to meet in relation to the rendering of Medicare eligible pathology services at facilities operated by the APA.

## **Part 2 – Legislation**

Part 2 lists the legislation that the APA undertakes to comply with under section 2 of Part 1 of Schedule 2.

### **Part 3 – Items an Authority may provide requesting practitioners**

Section 14 of Part 1 of Schedule 2 requires an APA to undertake not to accept a request for services where any benefit or incentive, other than an item set out in Part 3, has been directly or indirectly offered or supplied to the requesting practitioner. These items can only be used for the collection of specimens for pathology testing when supplied by pathologists to requesting practitioners. These are generally single use items employed in the collection of pathology specimens. The list of items may be updated from time to time, through amendment to this instrument, in consultation with the Royal College of Pathologists of Australasia.

### **Part 4 – Execution of undertaking**

Part 4 sets out the form of the execution of an undertaking by a person who wishes to become an APA.

## Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

### Health Insurance (Approved Pathology Undertakings) Approval 2017

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### Overview of the Legislative Instrument

Subsection 23DB(1) of the *Health Insurance Act 1973* ('the Act') provides for the Minister to approve forms of undertakings to be given by persons who wish to become approved pathology practitioners or approved pathology authorities. The current forms of undertaking are approved in the *Health Insurance (Approved Pathology Undertakings) Approval 2002* (the Undertakings Instrument 2002).

With the exception of some basic tests conducted by some medical practitioners within their own medical practice, Medicare benefits for pathology services are only payable when they are rendered by or on behalf of an approved pathology practitioner, in laboratory operated by an approved pathology authority. One of the requirements of becoming an approved pathology practitioner or an approved pathology authority is that the person has given an undertaking in the approved form and the Minister has accepted that undertaking.

The Undertakings Instrument 2002 is due to sunset on 1 October 2017. The *Health Insurance (Approved Pathology Undertakings) Approval 2017* (the Undertakings Instrument 2017) revokes and remakes the Undertakings Instrument 2002.

The approved forms of undertaking in the Undertakings Instrument 2017 set out obligations on approved pathology practitioners and approved pathology providers that ensure they are accountable for pathology services that are rendered by or on their behalf in an accredited pathology laboratory and with respect to their eligibility for Medicare rebates for pathology services. The overarching objective of the approved forms of undertaking is to ensure patient safety in the provision of pathology services

#### Human rights implications

The International Covenant on Economic, Social and Cultural Rights recognises that individuals have the right to the enjoyment of the highest attainable standard of health, including a right to a system of health protection.

The Undertakings Instrument will maintain rights to access quality, safe, clinically relevant and cost effective Medicare-pathology services.

If the new instrument is not made, no new pathologists can become Approved Pathology Practitioners (APPs) and no new pathology providers can become Approved Pathology Authorities (APAs). Additionally, given that APP and APA approvals are limited to a maximum duration of 1 year, current APPs and APAs would be prevented from being re-approved. This would have a significantly detrimental effect on the Australian public's access to Commonwealth subsidised pathology services, and therefore people's right to health and social security.

The APA Undertaking requires an APA to undertake to allow officers authorised by the Chief Executive of Medicare onto their premises and to take copies of documents. However, in the context of the compulsory pathology accreditation system in relation to Medicare benefits for pathology, it is legitimate for the Government to have effective measures in place that are aimed at assuring individuals access to high quality and safe pathology services.

The legislative instrument promotes the right to health as they are aimed at ensuring pathology laboratories providing Medicare-eligible pathology services provide safe and high quality services.

### **Conclusion**

This Legislative Instrument is compatible with human rights as it maintains existing arrangements and the protection of human rights

**Greg Hunt**  
**Minister for Health**