

EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973

Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017

Section 23DNA of the *Health Insurance Act 1973* ('the Act') provides for the Minister to determine, by legislative instrument, the principles to be applied in exercising his or her powers under section 23DN of the Act to approve in principle, or refuse to approve, premises as an accredited pathology laboratory. The current principles determined under section 23DNA are the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002* (the Pathology Principles 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. Principles approved under section 23DNA operate to ensure that appropriate standards are met and maintained in pathology laboratories at which Medicare-eligible services can be provided.

The Pathology Principles 2002 is due to be repealed on 1 October 2017 as a result of the sunset provisions in the *Legislation Act 2003*.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 (Accredited Pathology Laboratories – Approval) Principles 2017* (the Pathology Principles 2017) repeals the Pathology Principles 2002 and ensures the continued application of relevant standards in relation to the approval process for accredited pathology laboratories and rendering of pathology services in such laboratories for the purposes of Medicare.

The Pathology Principles 2017 sets out the criteria for different categories of accredited pathology laboratories, and also specifies the standards that must be met as part of the accreditation assessment for each category of laboratory and kinds of services provided in the laboratory. The overarching objectives of the Pathology Principles include promoting the delivery of reliable test results and reducing the risk of misdiagnosis in the provision of pathology services.

The Pathology Principles 2017 is largely consistent with the Pathology Principles 2002, however it includes:

- changes to modernise drafting in line with current drafting standards;
- updates to legislative references; and
- 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 Pathology Principles 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 references 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 Pathology Principles 2017 is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Pathology Principles 2017 commences on the day after it is registered.

Details of the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2017*

1. Name of legislative instrument

Section 1 provides that the title of the legislative instrument is the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2017*.

2. Commencement

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

3. Authority

Section 3 provides the authority for the Principles under subsection 23DNA(1) of the *Health Insurance Act 2017* (the Act).

4. Application of Principles

Section 4 sets out that on and after commencement, the Principles apply to the exercise of the Minister's powers under section 23DN of the Act in relation to applications made and approvals given both before and after their commencement.

5. Interpretation

Subsection 5(1) provides that terms used in the Principles, unless otherwise defined, have the same meaning as in the Act.

Subsection 5(2) defines certain terms used in the Principles.

Subsections 5(3) and (4) provide for the Minister to approve an organisation as an independent body in relation to a category M laboratory, and sets out the matters that must be taken into account.

Subsection 5(5) provides that a reference in the Principles to revocation of accreditation by an independent body or revocation of State accreditation includes other kinds of action which have the same effect as revocation, regardless of how that action is described.

Subsection 5(6) clarifies that a reference to an application for approval under section 23DN includes applications for variations of an approval to add a kind of service, change the category of approval, or extend the period of approval.

Part 2 – General

6. Purpose and objects of Principles

Section 6 outlines the purpose and objects of the Principles.

7. Weight to be given to views of independent body

Section 7 provides that when making a decision under section 23DN of the Act, the Minister must take into account the most recent advisory and assessment reports and accreditation action that relate to the premises, and may also take into account a report or action which is not the most recent. It also provides for the relative weighting the Minister should give where an independent body and an applicant or approval holder put forth differing views.

8. Action may be taken despite appeal or challenge

Section 8 provides that the Minister must continue to apply the Principles, including taking into account relevant reports and accreditation action, even where the report or accreditation action is subject to a review. It also provides that the Minister may review a decision under section 23DN where a relevant report or accreditation action is subsequently varied or set aside, but is not obliged to do so.

9. Assessment report by independent assessment body

Section 9 sets out the form and content requirements for assessment reports of laboratory premises provided by an independent body or special adviser.

10. Other matters taken into account in making decision

Section 10 outlines other matters that the Minister may take into consideration when making a decision under section 23DN of the Act in relation to the approval of a premises as an accredited pathology laboratory.

Part 3 – Approval of premises

11. Approval of premises

Subsection 11(1) provides that unless there are exceptional circumstances, the Minister must not give an approval in principle of a premises as an accredited pathology laboratory unless he or she is satisfied with a high level of confidence that pathology services to be rendered at the premises will meet the relevant standard for the relevant pathology services and category of laboratory, and that the premises will comply with relevant requirements of the Act, the Principles, and the accreditation materials.

Subsection 11(2) sets out that, subject to the exception provided for by section 12, the Minister must only consider an application for approval if he or she is provided with the most recent assessment report for the premises.

Subsection 11(3) provides that unless there are exceptional circumstances, the Minister must not give an approval in principle if certain kinds of specified accreditation action occurred in respect of the premises in the 6 months preceding the application for approval.

Subsection 11(4) provides that unless there are exceptional circumstances, the Minister must not give an approval in principle unless he or she is satisfied that the most recent assessment report provided under subsection 11(2) supports approval of the premises as an accredited pathology laboratory for the kind of services and the category of laboratory covered by the application for approval.

Subsection 11(5) provides that if a premises is not approved in principle pursuant to subsection 11(4), the Minister may deal with an amended application which amends the kind of services or category of laboratory as if it were an original application.

12. Approval in the absence of assessment report

Section 12 deals with circumstances where there is no assessment report provided by an independent body for the Minister to consider in relation to an application for approval of a premises as an accredited pathology laboratory. Subsections 12(1) and (2) provide for the Minister to consider such an application if an advisory report that accords with subsection 12(3) is provided with the application, and the application relates to a kind of service or category of laboratory for which the applicant does not hold an approval in principle or an approval under section 23DN of the Act in relation to the premises at the time the application is made.

Subsection 12(3) provides that unless there are exceptional circumstances, the Minister must grant an approval in principle in respect of such an application if it is supported by an advisory report which meets the specified content requirements.

13. Approval where there is a State accreditation system

Section 13 deals with circumstances where the State in which a pathology laboratory premises is located has an accreditation system which pathology laboratories may obtain accreditation for the kind of pathology services to which an application relates. It provides that in such circumstances, when making a decision under section 23DN the Minister must consider certain specified matters relating to the premises and the State accreditation system.

14. Period of approval

Section 14 sets out the periods for which the Minister may grant approvals and extensions to approvals of accredited pathology laboratories.

15. Revocation of approval

Subsection 15(1) outlines the circumstances in which the Minister must revoke an approval of a laboratory premises. Subsection 15(2) provides that this must be done within 28 days of the Minister learning that any of the circumstances specified in subsection 15(1) exist. Subsection 15(3) clarifies that section 15(3) does not limit the matters that may be taken into account when deciding whether to revoke an approval under section 23DN of the Act.

16. Variation of approval

Subsection 16(1) outlines the circumstances in which the Minister must make an appropriate variation to an approval under section 23DN of the Act. Subsection 16(2) provides that this must be done within 28 days of the Minister learning that any of the circumstances specified in subsection 16(1) exist. Subsection 16(3) clarifies that section 16 does not limit matters that may be taken into account when deciding whether to vary an approval under section 23DN of the Act.

Part 4 – Categories of premises

17. Allocation of categories

Section 17 sets out the categories of accreditation of pathology laboratories for the purposes of section 23DN of the Act and the criteria applicable to each category.

18. Standards of direction, control etc of premises required

Section 18 sets out the supervision standards for each category of laboratory specified in section 18.

Schedule 1 – Accreditation materials (until November 2017)

Schedule 1 sets out the documents that are accreditation materials until 30 November 2017. Standards set out in accreditation materials are relevant standards for the purposes of the Principles.

Schedule 2 – Accreditation materials (beginning on 1 December 2017)

Schedule 2 sets out the documents that are accreditation materials from 1 December 2017. Standards set out in accreditation materials are relevant standards for the purposes of the Principles.

Statement of Compatibility with Human Rights

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

Health Insurance (Accredited Pathology Laboratories – Approval) Principles 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

Section 23DNA of the *Health Insurance Act 1973* ('the Act') provides for the Minister to determine the principles to be applied in exercising his or her powers under section 23DN of the Act to approve in principle, or refuse to approve, premises as an accredited pathology laboratory. The current principles determined under section 23DNA are the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002* ('the Pathology Principles 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 key objectives of the Pathology Principles is providing a quality framework that requires pathology laboratories to meet certain standards in relation to the provision of pathology services in order for Medicare benefits to be payable for those services.

The Pathology Principles 2002 is due to sunset on 1 October 2017. The *Health Insurance (Approved Pathology Undertakings) Approval 2017 (Accredited Pathology Laboratories – Approval) Principles 2017* (the Pathology Principles 2017) repeals and largely remakes the Pathology Principles 2002, with changes to modernise drafting in line with current standards, update legislative reference, and assure consistency with other relevant legislation.

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 Pathology Principles 2017 will maintain rights to access quality, safe, clinically relevant and cost effective Medicare-pathology services.

If the new instrument is not made, no new pathology premises can be approved and current accredited pathology laboratories 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 Pathology Principles 2017 promote the right to health as they are aimed at ensuring pathology laboratories providing Medicare-eligible pathology services provide 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