



Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles 2021

I, Dr Megan Keaney, as delegate of the Minister for Health and Aged Care, make the following principles.

Dated 30 July 2021

Dr Megan Keaney
Acting First Assistant Secretary
Medical Benefits Division
Health Resourcing Group
Department of Health

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1 Name

This instrument is the *Health Insurance (Accredited Pathology Laboratories—Approval) Amendment (Relevant Standards) Principles 2021*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	31 July 2021
2. Schedule 1, Part 1	1 August 2021.	1 August 2021
3. Schedule 1, Part 2	1 January 2022.	1 January 2022
4. Schedule 1, Part 3	1 August 2022.	1 August 2022

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 23DNA(1) of the *Health Insurance Act 1973*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Part 1—Amendments commencing 1 August 2021

Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017

1 Subsection 5(2)

Insert:

pathology discipline with a national workforce shortage means any of the following pathology disciplines:

- (a) genomics (including cytogenetics and biochemical genetics);
- (b) immunology;
- (c) chemical pathology.

S(FC) laboratory has the same meaning as in the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)*.

2 Subsection 17(1) (cell at table item 1, column headed “Criteria”)

Repeal the cell, substitute:

Either of the following:

- (a) premises comprising a laboratory, or a number of co-located laboratories, that:
 - (i) are under the full-time onsite direction and control of a designated person, who is a pathologist; and
 - (ii) render services in 1 or more groups of pathology testing either:
 - (A) under the full- time supervision of a pathologist (whether or not the designated person) with the relevant scope of practice; or
 - (B) if the groups of pathology testing are in 1 or more pathology

- disciplines with
a national
workforce
shortage and the
laboratory, or
co-located
laboratories, are
unable to recruit
a full-time
pathologist with
the relevant
scope of
practice—under
the supervision
of a pathologist
(whether or not
the designated
person);
- (b) premises comprising a
laboratory, a number of
co-located laboratories or
a network of laboratories,
that:
- (i) are a recognised
national blood
service; and
 - (ii) are under the
full-time direction,
control and
supervision of a
designated person,
who is a
pathologist with the
relevant scope of
practice; and
 - (iii) render a limited
range of pathology
testing under the
full-time
supervision of a
pathologist
(whether or not the
designated person)
with the relevant
scope of practice.

3 Subsection 17(1) (table item 2, column headed “Criteria”, paragraphs (a) and (b))

Omit “is”, substitute “are”.

4 Subsection 17(1) (table item 2, column headed “Criteria”, paragraph (c))

Repeal the paragraph, substitute:

- (c) render services in 1 or more groups of pathology testing either:
- (i) under the full- time onsite supervision of a pathologist (whether or not the designated person) with the relevant scope of practice; or
 - (ii) if:
 - (A) the groups of pathology testing are in 1 or more pathology disciplines with a national workforce shortage; and
 - (B) the laboratory, or co-located laboratories, are unable to recruit a full-time pathologist with the relevant scope of practice;
- under the supervision of a pathologist (whether or not the designated person);

5 Subsection 17(1) (table item 3, column headed “Criteria”, paragraphs (a) and (b))

Omit “is”, substitute “are”.

6 Subsection 17(1) (table item 3, column headed “Criteria”, paragraph (c))

Omit “renders”, substitute “render”.

7 Subsection 17(1) (table item 5, column headed “Criteria”)

Omit “Either of the following”, substitute “Any of the following”.

8 Subsection 17(1) (at the end of the cell at table item 5, column headed “Criteria”)

Add:

- ; (c) premises comprising a laboratory that:
- (i) is under the full-time direction, control and supervision of a designated person, who is:
 - (A) a medical practitioner; and
 - (B) not a pathologist; and
 - (ii) renders a limited range of pathology testing:
 - (A) for a target patient population or of a specialised nature; and
 - (B) that is in 1 or more pathology disciplines with a national workforce shortage;
- (d) premises comprising an S(FC) laboratory that:
- (i) is under the full-time direction, control and supervision of a designated person, who is:
 - (A) a medical practitioner with a specialised scope of practice; and
 - (B) not a pathologist; and
 - (ii) renders a limited range of pathology testing that is:
 - (A) restricted to tests related to fertility control testing; and
 - (B) under the full-time supervision of the designated person.

9 Subsections 18(3) and (5)

Omit “*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)*”, substitute “*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)*”.

10 Subsection 18(5) (note)

Omit “*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)*”, substitute “*Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)*”.

11 At the end of section 18

Add:

- (6) Paragraph (1)(c) and subsection (4) do not apply to a designated person of a premises that:
 - (a) comprises a category S laboratory; and
 - (b) renders services in 1 or more groups of pathology testing that are in 1 or more pathology disciplines with a national workforce shortage.

12 Schedule 1

Omit “NPAAC materials”, substitute:

1 NPAAC materials

The following table has effect for the purposes of the definition of *accreditation materials* in subsection 5(2).

13 Schedule 1 (table item 19)

Repeal the item, substitute:

- | | | |
|----|--|------|
| 19 | Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021) | 2021 |
|----|--|------|

14 Schedule 1 (table item 21)

Repeal the item, substitute:

- | | | |
|----|--|------|
| 21 | Requirements for the Retention of Laboratory Records and Diagnostic Material (Eighth Edition 2021) | 2021 |
|----|--|------|

15 Schedule 1 (note at the end of the table)

Omit “2018”, substitute “2021”.

16 At the end of Schedule 1

Add:

2 Application of the *Requirements for Medical Pathology Services (Third Edition 2018)*

Scope

- (1) This clause applies in relation to a designated person of a premises that:
 - (a) comprises a category S laboratory; and
 - (b) renders services in 1 or more groups of pathology testing that are in 1 or more pathology disciplines with a national workforce shortage.

Application

- (2) For the purposes of this instrument, the *Requirements for Medical Pathology Services (Third Edition 2018)* (mentioned in table item 17 of clause 1 of this Schedule) apply, in relation to the designated person, as if the definition of *designated person* in those requirements did not include a reference to relevant scope of practice.

Part 2—Amendments commencing 1 January 2022

Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017

17 Schedule 1 (at the end of the table)

Add:

23	Requirements for the Communication of High Risk Pathology Results (First Edition 2020)	2020
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Part 3—Amendments commencing 1 August 2022

Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017

18 Schedule 1 (table item 4)

Repeal the item, substitute:

4	Requirements for Information Communication and Reporting (Fourth Edition 2020)	2020
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