

Guideline

Subject: Setting up a laboratory in Australia
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Review By: BPPQ
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The following information is aimed to assist pathologists who may be considering setting up their own laboratory. It is not an exhaustive list of considerations. Obtaining good professional, legal and financial advice should be sought.

Essentials before starting

Obtain reliable and trustworthy financial and legal advice concerning aspects of laboratory ownership, including but not limited to:

- A business plan, mortgages, interest repayments, short term credit.
- Business models, board, directors, company arrangements, ABN, GST, taxation.
- Conveyancing, leases, MoUs, other agreements such as contracts with senior staff, contracts with suppliers, business arrangements, Health Insurance Act.
- Legislation, regulations, accreditation: in order to bill Medicare directly (bulk billing) or privately bill patients (who then claim Medicare reimbursements).
- The pathology service must be assessed by NATA (NATA-RCPA scheme) to gain accreditation essential for Medicare billing. Medicare (Health Insurance Act and associated regulations) imposes the need to have:
 - Approved Pathology Authority undertaking (usually owner/CEO)
 - Approved Pathology Practitioner undertaking (nearly always pathologist specialist) – billing Medicare requires previous approval of APP undertaking and pathologist.
 - Approved Pathology Laboratory. A real laboratory has to be set up and fitted out for delivery of pathology services before NATA will perform site inspection/visit and advise Medicare of suitability of pathology service starting business. A full NATA assessment will be arranged within 6 months, and repeated every 2-3 years.
 - Provider number.
 - Specialist recognition.

Useful websites

The following websites may provide helpful information regarding legislation and accreditation requirements.

Australian Government Legislation

Health Insurance Act 1973:

http://www.austlii.edu.au/au/legis/cth/consol_act/hia1973164/

Health Insurance Amendment Act:

http://www.austlii.edu.au/au/legis/cth/num_act/hlaa21983288/

Corporations Act: http://www.austlii.edu.au/au/legis/cth/consol_act/ca2001172/

State Based Legislation:

NSW:

<https://www.legislation.nsw.gov.au/#/view/act/2010/127>

QLD: <http://www.health.qld.gov.au/publichealthact/>

SA:

<https://www.legislation.sa.gov.au/LZ/C/A/SOUTH%20AUSTRALIAN%20PUBLIC%20HEALTH%20ACT%202011.aspx>

TAS: <https://www.legislation.tas.gov.au/view/html/inforce/current/act-1997-086>

VIC:

[http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubStatbook.nsf/f932b66241ecf1b7ca256e92000e23be/8B1B293B576FE6B1CA2574B8001FDEB7/\\$FILE/08-46a.pdf](http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubStatbook.nsf/f932b66241ecf1b7ca256e92000e23be/8B1B293B576FE6B1CA2574B8001FDEB7/$FILE/08-46a.pdf)

WA:

https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13787_homepage.html

NT:

<https://legislation.nt.gov.au/en/Legislation/PUBLIC-AND-ENVIRONMENTAL-HEALTH-ACT>

NATA: <http://www.nata.asn.au/>

NPAAC: <http://www.health.gov.au/npaac>

Department of Health and Ageing: <http://www.health.gov.au/>

Medicare Australia: <http://www.medicareaustralia.gov.au/>

MBS Online: <http://health.gov.au/mbsonline>

Australian Digital Health Agency: <https://www.digitalhealth.gov.au/>

RCPA Quality Assurance Programs Pty Limited: <http://www.rcpaqap.com.au/>

Therapeutic Goods Administration: <http://www.tga.gov.au/>