



GUIDELINES FOR  
ESTABLISHING ON-SITE  
PATHOLOGY COLLECTION  
CENTRES FOR GENERAL  
PRACTITIONERS



AAPP



AUSTRALIAN ASSOCIATION OF PATHOLOGY PRACTICES INC

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## Introduction

The Australian Association of Pathology Practices (AAPP) has been asked to provide advice and information regarding compliance with legislation for Approved Pathology Collection Centres (ACCs) located within medical practices.

The purpose of the brochure is to provide General Practitioners (GPs) with a guide to the issues they need to consider in the process of agreeing to establish a collection centre within a general practice.

The information provided in this brochure relates to:

### 1 Standards for Establishing Collection Centres

### 2 Legislative Compliance

### 3 Lease Agreements

Please note the advice provided cannot and should not be construed as being legal advice. GPs are strongly encouraged to seek their own legal advice before entering any arrangements with pathology providers.

Additionally, more information is available from the AAPP and the Royal Australian College of General Practitioners (RACGP).



## Standards for Collection Centres

GPs should be aware that pathology providers are bound by regulations relating to establishing and operating collection centres. Collection centres need to meet those standards in order to be accredited. It is only then that specimens collected in the centre are eligible for Medicare Benefits Schedule rebates.

Whilst in the main the standards apply to pathology providers, GPs need to be aware of the standards as they will impact upon the layout and design of their premises.

The following information has been summarised from the National Pathology Accreditation Advisory Council (NPAAC) ACC standards. All collection centres must ensure that these standards are adhered to in all of their collection facilities. The information is grouped into the areas listed below.

- Premises
- Staffing
- Equipment
- Documentation and Instruction
- Collection Procedures
- Safety
- Transport and Storage of Specimens



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## 1. Premises

There are a number of applicable standards relating to the collection premises. Premises must comply with all applicable laws and regulations.

The size and location of collection areas must be appropriate for purpose and there should be reasonable access provided for ill and disabled patients, including wheelchair access. Hours of operation should be displayed.

There must be appropriately designated areas for reception, waiting and collection, which must not compromise patient privacy and confidentiality of information. These areas do not have to be separate rooms.

Unauthorised persons must not enter collection rooms and there should be provision to accommodate carers as required.

Ventilation, lighting, plumbing, communication systems and temperature control must be adequate and appropriate for the safe and comfortable functioning of the collection premises.



## 1. Premises (continued)

Appropriate hand-washing facilities must be conveniently available to collection staff and adequate toilet facilities must be available for patients, staff and accompanying persons in, or conveniently adjacent to the collection centre.

Additionally, toilet doors should be lockable from the inside and unlockable from the outside in case of an emergency. The doors should be removable or open outward for access.

Easily cleanable surfaces must be available for clerical work, specimen collection and specimen handling. Suitable tables and a secure storage area for supplies must be available and accessible to staff only.

Finally, there must be easily cleaned floor coverings appropriate to the use of that area. For example, floor coverings in the immediate collection and storage areas must have a non-porous surface.



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## 2. Staffing

Staff numbers must be appropriate to the throughput of the centre. Appropriate identification must be worn by all staff displaying a first or last name and an organisation name as a minimum.

Appropriate attire must be worn by staff. Attire should be in accordance with the APA's policies.

Continuing education and training and ongoing performance reviews must be relevant to the job being performed and relevant standard (AS ISO 151892).

Staff must be aware of existing policies regarding privacy, confidentiality and informed consent and comply with the policies. The specimen must be collected in accordance with these policies also.

Staff must be trained to ensure knowledge of basic first aid to deal with situations likely to be encountered in the course of collection. Evidence of such training should be documented for each trained staff member.



### 3. Equipment

It is essential to provide and maintain all equipment listed below (materials must not be used past their expiry date):

- a suitable collection chair and couch for patients
- materials required for adequate specimen collection
- basic first aid equipment
- approved receptacles for sharps and for contaminated waste
- materials required for management of biohazard spills.

Appropriate resuscitation equipment must also be available for use by trained personnel when complicated procedures are performed, for example, the injection or infusion of any substance.

There must also be dedicated specimen storage areas, including suitable, securely-placed refrigerators and appropriate, secure, room temperature storage. Specimens must not be stored with food, drink or pharmaceuticals and should be stored for the least possible time prior to transport.

If a centrifuge is required, it must be compliant with AS/NZS 2243.33. Maintenance and service records for centrifuges must be available on request, including a report of an annual check.

Some collection centres perform more than just collections. All equipment used for other procedures, for example ECG, must comply with the appropriate standards.



## 4. Documentation & Instruction

Collection instructions must be available for all procedures including those where patients collect their own specimens. Manuals can be in electronic form or hard copy and should conform to AS ISO 151892.

Documented procedures for handling emergencies must be understood and available for immediate reference and a protocol for management of biohazard exposure, including spills, must also be available.

In addition, maximum allowable storage time should be specified in the collection instruction manual.





## 5. Collection Procedures

The collection centre must have written procedures for the identification of patients and labelling of specimens.

Prior to collection, the patient must be informed of the procedure about to take place. Patient comfort and safety with the full procedure should be assured.

Collection procedures must be in accordance with the laboratory's procedures manual.

For blood collection, specimens must be labelled immediately following collection while still in the presence of the patient. The patient should be asked to confirm that the name on the label is correct.

Patients must be instructed on post-procedure care in accordance with the laboratory's instruction manual.



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## 6. Safety

The collection centre must conform to OH&S legislative requirements. Further safety requirements are summarised in the four key points below:

- minimisation of infection risk should be clearly demonstrated
- collection centre staff must use personal protective equipment where appropriate
- APAs must have a vaccination policy
- transport and disposal of waste must be carried out in accordance with laboratory policy and applicable regulatory requirements.

## 7. Transport and Storage

Collection centres must comply with the current NPAAC requirements for transport and storage. Further information can be found in the *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials*).

If specimens are to be retained within the collection centre, safety, specimen stability and security requirements must be addressed and appropriately documented. The security procedures specified must ensure that the specimens are not accessible to members of the public.



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## Legislative Compliance

In March 2008, the laws were changed such that they are more relevant, including binding both pathology providers and requestors into compliance with them. There are a number of compliance issues to consider relating to ACCs located within premises owned and/or occupied by requesting medical practitioners who request pathology services or persons who are, for these purposes deemed to be pathology requesters.

In order to be compliant with the prohibited practices legislation relating to ACCs, arrangements between pathology providers and requestors of pathology services must satisfy certain criteria. The criteria are set out within the Health Insurance Amendment (Inappropriate and Prohibited Practices and other Measures Act 2007) and the Health Insurances Amendment Regulations 2009 (No. 2).

The legislation is designed to prevent the payment of inappropriate and unethical benefits from a pathology provider to a pathology requester. The legislation also prohibits requestors from soliciting benefits from pathology providers valued such that they recognise the referral income stream derived by the pathology provider. However it is not intended to prohibit legitimate commercial transactions. Benefits provided can include cash, property, goods and services.



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## Legislative Compliance (continued)

Importantly the prohibited practices laws apply to both pathology providers and pathology requesters, GPs. Consequently, penalties for non-compliance apply to both parties. There are substantial civil law penalties, fines of up to \$660,000 and in addition penalties of up to five years imprisonment, operating under the criminal law.

Medicare Australia is the body that oversees issues of compliance and has created a Prohibited Practices Taskforce. The taskforce will focus on providers and companies suspected of offering inducements to requesters in return for requests for their services and requesters, GPs who seek prohibited benefits.

Some benefits are permitted under the legislation but only if the benefit is not related to the number, kind or value of requests for pathology services made by the requester, is provided at market value and does not consist of the provision of staff or equipment by the provider other than for the purpose of providing pathology services within an ACC.

Pathology providers are able to provide requestors with certain approved products or services free of charge, including consumables providing they are used solely in the collection of pathology specimens.



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## Lease Agreements

There is no fundamental impediment to a pathology provider and requester entering into a lease relating to the establishment of an ACC. There are however certain rules and requirements which must be adhered to. A lease relating to an ACC must satisfy three essential conditions to be compliant for both the pathology provider and the requester. They are:

- that the rent is not substantially different to the market value of the rent for the premises
- the rent does not include any sum relating to the number, kind or value of requests for pathology services
- the pathology provider must establish an ACC within 60 days of entering the arrangement and must not use the premise for any other purpose.

In determining market value, some value may be attributed to the convenience of the location with regard to patient access. In essence, market value, subject to satisfying the 2<sup>nd</sup> requirement noted above, assumes an arms-length transaction with each party acting knowledgeably and without compulsion.

The legislation defines “not substantially different to market value” as being a sum being paid that is not more than 20% greater (or lesser) than the agreed compliant market value.



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## Lease Agreements (continued)

There is a further and critical determinant to be satisfied before an ACC lease agreement is compliant. There must be no component included in the lease payment relating to the number, kind or value of requests for pathology services. Severe penalties apply.

If the rent being negotiated for the collection centre is significantly higher than other comparative rents, it is likely the rent includes an attribution of value for the requested pathology services.

For example, if the head lease over the GP premise or rent charged by a GP to a sub-tenant was \$250 per square metre per annum and the proposed pathology ACC rent per square metre per annum was \$2,500 per square metre, it is likely that the rental arrangement is prohibited. It would be hard to avoid the conclusion that there is a sum related to the revenue derived by the pathology provider from requests for pathology services included in the rental payment.

The department of Health and Ageing published a booklet entitled, *“Changes To Laws Relating to Pathology and Diagnostic Imaging”*. It is available on their website and is recommended as an informative source of advice regarding compliance matters.



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