

## Guidelines for establishing on-site Pathology collection centres for General Practitioners

### Introduction

Pathology Australia (PA) 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 PA and the Royal Australian College of General Practitioners (RACGP).

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

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.

## **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.

## **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.

## **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.

## **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 Insurance 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.

Importantly the prohibited practices laws apply to both pathology providers and pathology requestors, 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 requestors in return for requests for their services and requestors, 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.

## **Lease Agreements**

There is no fundamental impediment to a pathology provider and requestor 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 requestor. 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 second 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.

### **Lease Agreements**

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.

## Bibliography

1. Health Insurance Act 1973, Commonwealth of Australia, Australian Government, Canberra, viewed 21 November 2008, <http://www.comlaw.gov.au>
2. AS ISO 15189 – 2009 Medical Laboratories - Particular Requirements for Quality and Competence, Standards Australia
3. AS/NZS 2243.3:2002/Amdt 1:2003 – Safety in laboratories - Microbiological aspects and containment facilities, SAI Global
4. NPAAC (2007), Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials, Commonwealth of Australia, Australian Government Department of Health and Ageing, Canberra

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