



Pathology (Approved Collection Centres) Roundtable on Compliance

BCG Report of Roundtable held on 27 April 2016

17 May 2016

THE BOSTON CONSULTING GROUP

This Report

The Australian Government Department of Health commissioned The Boston Consulting Group (BCG) to independently facilitate a Roundtable on compliance for approved pathology collection centre rents. The Roundtable was held on 27 April 2016 at BCG's Canberra offices, with participants drawn from across the health sector involved with the question of rents for pathology collection centres in Australia. This Report is a report on the Roundtable discussion, the process we undertook, and independent observations stemming from the Roundtable.

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1 Context of the Roundtable

The Roundtable was initiated by the Australian Government, in response to concerns by many in the pathology sector about high rents for co-located Approved Collection Centres ('ACC'). The objective of the Roundtable was to provide a forum to understand the opinion of major involved organisations on the issue of rents, including issues with the status quo, regulatory interpretation, and compliance activities. Participating organisations represented pathology providers, pathology representative and professional bodies, general practice representative and professional bodies, and the Department of Health.

Prohibited practices

Section IIBA of the *Health Insurance Act 1973* was introduced in 2008 to prevent inducements and other inappropriate relationships between requestors and providers of medical services. This section defines a number of relationships where regulations on prohibited practices apply. For the pathology sector, these regulations apply where benefits flow between pathology requestors or parties "connected" to requestors, and pathology providers or those "connected" with providers, where "connecting" relationships are tightly defined. These regulations prohibit ACC leases secured on the basis of requestors referring some or all of their patients to pathology providers or on the basis of setting rent on the value of services referred. For parties falling under the prohibited practices regulations, payments flowing between them must not be substantially different from the "market value" of the property, goods, or services exchanged.

Deregulation of ACCs

In 2010 legislation was amended to remove restrictions on the number of ACCs a pathology provider could open. Specifically, the Health Insurance (Eligible Collection Centres - Approval) Principles 2008 were repealed and replaced by the Health Insurance (Eligible Collection Centres - Approval) Principles 2010.

Previously, a complex formula was used by the Department of Human Services to allocate the number of new ACC approvals for each pathology provider, which significantly limited the creation of new centres. Pathology providers applied for more ACC approvals under the new legislative regime, leading to increased numbers of co-located pathology collection centres and medical clinics. Total ACCs increased substantially, with the Department of Health reporting an increase from 2,662 in 2010 to around 5,400 by April 2016.

The rise in co-located ACCs changed the competitive dynamic between pathology providers as the convenience of co-location offered high numbers of collections. As a result, competitive pressures for co-located ACC space pushed up rents per square metre.

2 Roundtable participants

At the direction of the Government the Department of Health commissioned BCG to independently facilitate a Roundtable on compliance for approved pathology collection centre rents. The Roundtable took place on 27 April 2016 at BCG's Canberra offices, with participating organisations from across the health sector who are involved with the issue of rents for pathology collection centres in Australia.

Before the Roundtable, BCG spoke with each participant to understand their views on the issue of Approved Collection Centre rent and compliance.

Roundtable participants are listed below in alphabetical order.

- **Australian Clinical Labs:**
 - Melinda McGrath – CEO

- **Australian Independent Pathology Association:**
 - Dr Wayne Smit – Convenor

- **Australian Medical Association:**
 - Dr Bev Rowbotham – Chair, AMA Federal Council & Pathologist
 - Dr Brian Morton – Chair, AMA Council of General Practice
 - Alexander White – Policy Director, Medical Practice
 - Warwick Hough – Policy Director, General Practice, Legal Services and Workplace Policy

- **Catholic Health Australia:**
 - Patrick Tobin – Director of Policy
 - Michael Hogan – CEO, St John of God Health Care Pathology

- **Department of Health:**
 - Andrew Stuart – Deputy Secretary
 - Jaye Smith – Assistant Secretary, Primary Care and Diagnostics Branch, Medical Benefits Division
 - Ben Noyen – Assistant Secretary, Health Compliance Branch, Health Provider Compliance Division
 - Joanne Tester – Director, Pathology Section, Primary Care and Diagnostics Branch, Medical Benefits Division

- **Pathology Australia:**
 - Dr Nick Musgrave – President
 - Liesel Wett – CEO

- **Primary Health Care:**
 - James Bateman – General Manager, Pathology
 - Alex Smith – Group Director, Strategy

- **Public Pathology Australia:**
 - Jenny Sikorski – CEO

- **Royal Australian College of General Practitioners:**
 - Dr Neville Steer – GP Advocacy & Support Standing Committee
 - Roald Versteeg – Program Manager, Policy & Practice Support

- **Royal College of Pathologists of Australasia:**
 - Dr Michael Harrison – President
 - Dr Debra Graves – CEO

- **Sonic Healthcare:**
 - Dr Colin Goldschmidt – CEO, Sonic Healthcare
 - Dr Ian Clark – CEO, Sonic Pathology

3 Summary of the Roundtable

3.1 Current approach, and implications

3.1.1 Department of Health compliance approach

The Department provided an overview of the regulatory framework relating to ACC arrangements, and the background to compliance activities undertaken on ACC rents. This included the transfer of responsibility for provider compliance and ‘pathology collection centre’ compliance from the Department of Human Services (DHS) to the Department of Health (the Department) recently.

The Department also described the DHS Prohibited Practices Taskforce in 2010. The Department noted that the Taskforce had found minor infractions relating to improper treatment of samples, but found no major compliance breaches for rent based on the application of the “market value” test used by the Taskforce.

Interpretation of “market value” of rent

Prohibited practices regulations prohibit situations where pathology providers are leasing space for ACCs from requestors, or parties “connected” to requestors, and rents paid are substantially different from “market value”. The “market value” test does not apply in respect of all benefits paid for property, goods or services however. If the benefit is payment for property goods or services that are shared between the beneficiary and another person, the market value of the property is not relevant. The interpretation of “market value” is key in determining for many instances whether rents constitute breaches and what compliance actions are warranted. BCG understands the Prohibited Practices Taskforce’s investigations interpreted “market value” based on prices agreed to (in our rough and imprecise paraphrasing) between ‘willing pathologist buyers’ and ‘willing medical facility landlord sellers’, which was consistent with the method for determining market value laid out in section 20CB of the *Health Insurance Regulations 1975*.

The Department of Health acknowledged that the interpretation was contentious, given the alternate interpretation referenced by the SC engaged by Pathology Australia in his opinion. Given this, the Department advised that they would seek advice from the Australian Government Solicitor on the correct application of “market value” provisions.

Compliance approaches

The Department described its compliance activity as ‘responsive’. It has not received many complaints via the tip-off hotline and had no evidence that rents were substantially above “market value” as they currently interpret the regulations.

The approval/renewal process for new ACCs is performed by the Department of Human Services. While approval or renewal is not tied to rent level, simple data on rent is collected during the process. As the process is paper-based, the Department currently cannot compare rents over time or by geography. Potential contravention of the prohibited practices regime is, we understand, not one of the allowable criteria to be checked as part of approval or renewal of licenses, nor is potential contravention checked in parallel to the license process.

3.1.2 Participant views on the current ACC compliance regime

Perceived issues arising from the status quo

Most, but not all, Roundtable pathology participants expressed strong dissatisfaction with the current compliance regime and ranked high rents as a significant threat to the pathology sector. These participants represent, we understand, well over half the pathologists in Australia, and contended:

1. Smaller laboratories, such as independent, public and Catholic Health laboratories, are unable to pay the high rents and are withdrawing or will withdraw from the market
2. Cost-cutting to “afford” high rents is leading to a decrease in training and quality activities; and
3. Competition between pathology providers for co-located ACC leases is driven, in a material way, by ability to pay.

A minority of participants, including some from the pathology sector, believed the status quo is a fair interpretation of the regulations and supports fair outcomes. They believe that co-located rents are not coerced, given that pathology providers are not required by law to co-locate ACCs. They also felt that high rents were fair rewards for GP practices and the value of pathology proximity to these practices. Finally, these participants did not agree that quality was harmed and noted the stringent minimum standards that all laboratories must adhere to under the National Association of Testing Authorities.

What is “market value” rent?

Most participants thought that the legislation and the explanatory brochure on regulations did not offer sufficient clarity on “market value” rent. Different views of “market value” and permitted payments informed the views of participants on their compliance obligations.

Pathology Australia circulated a legal opinion on interpretation of “market value” it had commissioned from a Senior Counsel. It is the opinion of this Senior Counsel that the Act and regulations require a “traditional valuation exercise” based on a hypothetical transaction in which the identities of both parties are unknown. This should lead to prices “divorced from the identity of the parties, the relationship between them and any collateral advantage which the lessee (pathology provider) might expect to receive as a consequence of entering into the lease”. His opinion was also that the current interpretation of “market value” by the Department means that whatever rent is paid by willing pathologists is by definition the “market value”, so that it is very difficult to conceive of a scenario in which a payment would be 20% above “market value”.

This opinion was not supported by a minority of participants, noting that BCG had asked that the Roundtable not be a forum for settling the law via opposing barrister opinions.

One participant noted that, if the Pathology Australia SC’s opinion is correct, then when it comes to current rents, all participants behave contrary to the law, which seemed to them unlikely. They contended that rental practices were defensible based on internal legal opinions different to that of the Pathology Australia Senior Counsel, noting that they had seen a legal opinion from a general practice clinic owner to support this claim.

The Department acknowledged that the interpretation was contentious, given the alternate interpretation referenced by the SC engaged by Pathology Australia in his opinion. Given this, the

Department advised that they would seek advice from the Australian Government Solicitor on the correct application of “market value” provisions.

What is “substantially above” market value rent?

All participants were comfortable with “+20%” as a ‘bright line’ to define rents substantially above market value.

What relationship to potential pathology testing volumes is prohibited?

Section 23DZZIF of the *Health Insurance Act 1973*, generally excludes benefits from being permitted benefits if they are “related to the number, kind or value of requests for pathology services... made by the requester”. Participants disagreed on whether current high rents are prohibited on this basis. While some felt the regulation was intended to prevent kick-backs, others felt that rental payments based on best estimates of pathology testing volumes a provider might hope to receive (without collusion of estimates between lessees or lessors) are non-permitted benefits under this regulation.

Compliance approaches

Most participants felt that compliance on ACC rents has not been sufficiently pro-active noting that compliance has historically been the responsibility of DHS until the transfer of responsibility to the Department of Health in September 2015, by administrative arrangements order. One participant reported presenting the Department with sensitive commercial documents relating to an ACC rent that they thought was above market value that had not yet been followed up. However, participants also acknowledged that the tip-off hotline was not used because rents are commercially sensitive and generally only known to the lessor and the lessee. Unsurprisingly, these parties are reluctant to use the hotline.

Most participants also felt the Department had sufficient evidence to conduct compliance activities based on rents reported to DHS during the approval/renewal process. The Department noted that rents contravening prohibited practices were currently not a factor that could be considered in the approval/renewal process, as compliance and license approval/renewal were independent decisions. The Department noted that under the current interpretation of “market value” rents did not appear to be substantially above “market value”.

3.2 Participant proposals for the way forward

Following discussion, four primary proposals or options emerged or coalesced:

	Proposer	Compliance process	“Market value” interpretation
1.	Status quo	Audits where tip-offs received	(Implicitly based on) willing pathologists’ ‘prices’ in competitive bid process
2.	Department of Health	Increased data capture and analysis to inform targeted compliance investigations	[No proposal made]
3.	Royal Australian College of General Practitioners	Broadly supportive of Department proposal	Willing pathologists’ ‘prices’ in competitive bid process
4.	Pathology Australia	Broadly supportive of Department proposal, plus screen rents at point of approval/ renewal for compliance, initially via some form of database. Ultimately a Certified Practising Valuer’s valuation would need to be sought for rents outside the database benchmark for the area to establish compliance. Ad hoc compliance investigations also expected.	Rents for medical facilities in the area as per their Senior Counsel’s opinion

3.2.1 Status Quo

A full description of the status quo and participant views is provided in section 3.1. No participant endorsed continuing with the status quo.

3.2.2 Department proposals to strengthen compliance (note: no proposal made on interpretation of “market value” rent)

The Department advised that its current compliance strategy arises from Ministerial direction to increase compliance activity and identify high rents linked to non-permitted payments under the current legislative framework.

Interpretation of “market value” of rent

The Department did not propose an interpretation of “market value” for its future compliance activities.

Compliance approaches

The Department’s proposal was to improve data capture and methods to search for and identify non-permitted payments based on variance in rents, and increasing communication with the pathology and general practice sectors about the current regulatory approach. This would involve:

- Amending the Health Insurance (Approved Pathology Undertakings) Approval 2002, to improve data collection for compliance activities. This is still under consideration.

- Using data analytics to benchmark rental rates and target compliance activities.
- Analysis of Medicare data to identify providers or practices with unusually high requesting rates, regardless of rent, or those Approved Pathology Practitioners (APPs) with high self-requesting rates.
- A combination of audits and targeted letters to providers or practices with unusually high requesting rates or where there is a concern of non-compliance.
- Trials of strategies to educate and encourage voluntary compliance with the regulations.
- Promotion of the Fraud Hotline in the pathology sector to encourage the provision of tip-off information in relation to potential inducement activities.
- Updating the provider education material regarding the laws relating to pathology.

3.2.3 Royal Australian College of General Practitioners (RACGP)

Interpretation of “market value” of rent

RACGP and a minority of pathology participants supported an interpretation of “market value” based on the price paid by willing pathologists in a competitive bid process.

Compliance approaches

The RACGP supported the Department’s proposal for increased compliance activities, as described above in 3.2.2.

3.2.4 Pathology Australia

Interpretation of “market value” of rent

The majority of pathology participants and the AMA participants broadly supported Pathology Australia’s proposal, provided it was introduced in a way that provided sufficient time and notice to all providers.

Pathology Australia proposed the Senior Counsel opinion of the interpretation of “market value” outlined above in 3.1.2 be adopted by the Government.

Compliance approaches

Pathology Australia proposed that all ACC applications and renewals should include a formal valuation by an independent Certified Practising Valuer of the space to be leased. This valuation would be funded by the pathology provider that is making the application. To reduce the need for yearly valuations, when ACCs are due for renewal the original valuation may be adjusted for inflation instead of obtaining a new valuation. The valuation criteria could include unique practice factors, such as quality of current fit-out, as long as they were not taken as proxies for the value of potential referrals.

The application would need to include details of all payments made by the provider, including prepayments of rent and holding fees, and other benefits provided to the landlord (e.g. fit-out costs, payments for carpark spaces, and staffing/administrative costs). Professional valuers were believed to have frameworks for complex contractual arrangements, and full oversight of payments and services to lessors would thus be captured in applications.

Supporters of the proposal all felt that compliance should be done at the point of ACC approval/renewal applications, and that application approval should be contingent on proving compliance with rent regulations at this time. This would involve showing that the total rent paid, including extra payments, was not more than 20% above the certified valuer's opinion of value in order to comply with regulation 20CA of the *Health Insurance Regulations 1975*. This would not preclude further ad hoc compliance activity, especially to verify the accuracy of rental information supplied during the process.

One participant suggested that a professional valuation could supplement, as a second filter, an underlying database of rents coupled with a digital ACC approval/renewal portal that would constitute a first 'filter' that rents did not breach the non-permitted practices rules. The database would contain information on rents paid by ACCs in all locations, as well as commercial data on rental prices for medical clinic space. A professional valuation firm could run the database as it would be likely to have access to a larger dataset with private rental information. Under this system, the database could act as an initial screen. If the rent on the ACC application was not more than 20% above comparable medical space rentals in the database, then a valuer's opinion would not be required and an application could be automatically approved by the portal. If the rent was higher than 20% above the relevant database rents, a valuer's opinion would be required to establish that the rents did not contravene the non-permitted practices rules.

Participants in favour of this approach supported costs being recovered from the pathology sector to fund compliance. Higher ACC approval fees could cover the cost of digitising the ACC application and renewals process, and database implementation or outsourcing. Pathology providers would pay for certified valuations when making ACC applications, even those obtained by GPs.

Supporters agreed that this proposal would require significant communication with the sector, again the costs of which would be borne by the sector. Pathology providers and requesters would need to be made aware of their responsibilities under the Act via explanatory guidelines that outline these responsibilities and the compliance measures that will be introduced. A participating GP noted that communicating with the GP sector would need to be extensive, and that direct communications from the Department would be needed.

All participants agreed that based on the "market value" interpretation of this proposal, a large proportion of the sector's current rents, agreed in line with the Department's historic approach to "market value", would not be compliant. The Roundtable discussed the need for a short grace period after any move to different interpretations of "market value". A one-year transition period was discussed.

Participants in favour of this proposal argued that this proposal would shift the nature of competition for co-located ACC space more towards quality provided to pathology service requestors and their patients, and less based on rental payments to lessors. Participants not in favour believed that competition and quality is currently fair and appropriate, and worried that lessors have come to expect high rental incomes and would suffer under different interpretations.

3.3 Discussion on proposals: General areas of consensus

There was broad agreement on a number of dimensions.

Participants agreed with a “+20%” threshold for rent being “substantially higher” than market, even while holding strenuously different views on the correct interpretation of “market value”.

Again, notwithstanding very different views on “market value”, all agreed that speedy clarity on the Department’s interpretation of “market value” rent would enhance pathology market certainty around what is prohibited.

All agreed that co-located ACCs are good for patient convenience, and that co-located ACC lessees should not be awarded tenancy based solely on rents paid to lessees, but rather, quality of service provided should always be a consideration factor.

All agreed that the sector should strive to ensure there is no public perception of impropriety in rental agreements between lessors and lessees for co-located ACCs. All agreed that there was no suggestion of any ‘rent’ being contracted in the form of an explicit payment per referral. Rents paid must be transparent for compliance purposes, with clearly disclosed and reported data on major items paid for space, car-parks, major fit-outs, etc.

3.4 Discussion on proposals: General areas of disagreement

Participants disagreed vigorously on the interpretation of “market value” in the regulations, and whether this interpretation should be based on what ‘willing pathologists’ would pay, or what typical local medical facility rents would be adjusted on a pro-rata basis for space. There was also some discussion as to whether higher rents in anticipation of higher (non-guaranteed) referral volumes could be seen to be “related” to referrals and thus in contravention of the non-permitted practices provisions.

Participants did not agree on one proposed compliance approach, but much of the difference actually centred on different approaches to the question of “market value”. For any one definition of “market value” there was some brief discussion as to the cost and delay that might be incurred by different compliance approaches, however, there was not time to work these through in detail. The Department reminded the Roundtable that, under the current Regulations, compliance with the permitted practices provisions is not currently a factor that can be considered in relation to license approval and renewal.

4 BCG's independent observations

4.1 Interpretation of “market value” rent

A lack of clarity regarding the interpretation of “market value” rent underpins the current issue. All participants agree a clear interpretation would be useful to their activities. More meaningful, sustainable and certain compliance activities can only commence when the interpretation of “market value” is more settled.

Providing a clearer interpretation of “market value” rent can be achieved in different ways:

- 1) The Department committed to seeking a legal opinion from the Australian Government Solicitor as to their opinion of the correct interpretation of “market value”. This commitment was re-iterated by the Minister of Health in her letter to the pathology sector after the roundtable had concluded. The Department may then base its compliance activities on the Australian Government Solicitor’s interpretation, which may or may not lead to a change in practices.
- 2) Should further certainty be required, at least two avenues are possible:
 - a) The Department, or an aggrieved stakeholder, might wish to pursue legal action on the basis of their interpretation. This would allow the opportunity for the court to rule on the matter of the appropriate interpretation of “market value”.
 - b) The Government could have that, or any other interpretation, of “market value” written into a regulatory instrument, providing the appropriate processes for such an instrument were followed.

BCG observes that, at the very least, the first approach (1) would provide the government with a firm basis for its own activities, and ought to be proceeded with. Either 2a or 2b, or 2a followed by 2b, would then provide for even greater certainty if needed.

4.2 Timing of when any ‘new’ interpretation of “market value” would be acted upon

If the Government was to adopt in any way an interpretation different to the historic interpretation of the Department of Human Services (as implicitly carried on by the Department of Health to date), consideration would need to be given to the point in time at which that ‘new’ interpretation of “market value” would be acted on by the Government in relation to prohibited practices. It may be, for each licence, from the time of the next renewal of the licence, or a different time. Consideration will also need to be given to GPs, who have contracted in line with a practice widespread across the country, and considered compliant to date by the Departments concerned under their interpretation of “market value”.

4.3 At what point in the administrative process should compliance activities take place

All participants were comfortable with the Department conducting compliance activities whenever the Department had reason to believe that non-permitted practices might be taking place, either through a tip-off or data analysis.

However, many Roundtable participants also advocated a compliance check within the licence approval and renewal process.

Different approaches include the following, non-exhaustive, list:

- Compliance activity can be integrated with the ACC approval and renewal process so that every license approval and renewal is conditional on rents being individually proven to not substantially exceed “market value” – this would appear to be the most costly approach and burdensome on the Government and sector.
- Compliance activity can be integrated with the ACC approval and renewal process in a more risk-weighted way, so that compliance activity is done alongside approval and renewal, but individual prior checking of every rent is not a condition precedent for a license or renewal.
- Compliance activity can happen largely independent of, and typically after, the ACC approval and renewal processes.

We observe that different approaches have:

- Different need to change Regulations – as some will require change, others may not; and
- Different implications for costs to the pathology sector – as some approaches will cost significantly more than others, and all participants agreed that compliance costs would be funded by the pathology sector if it eventuated that “market value” should be interpreted closer to the ‘typical next best non-pathology use of such a medical facility’.

The Government will need to explore the costs and benefits of these different approaches in relation to its approach to the interpretation of “market value”.

4.4 The difference between how compliance checking is done, versus what the law is

As described above, many participants proposed tools, including databases of rents, car-parking, fit-out and ancillary costs, to assist both lessees and lessors and the Department identify where rents might be substantially above “market value”. It was suggested that Certified Practising Valuers might be engaged for greater precision where rents appear outside a database range.

Careful consideration will have to be given to how complex or simple these tools are; what the limit on numbers of valuations is between aggrieved parties; and how these tools are used by the Department to guide their compliance activities.

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