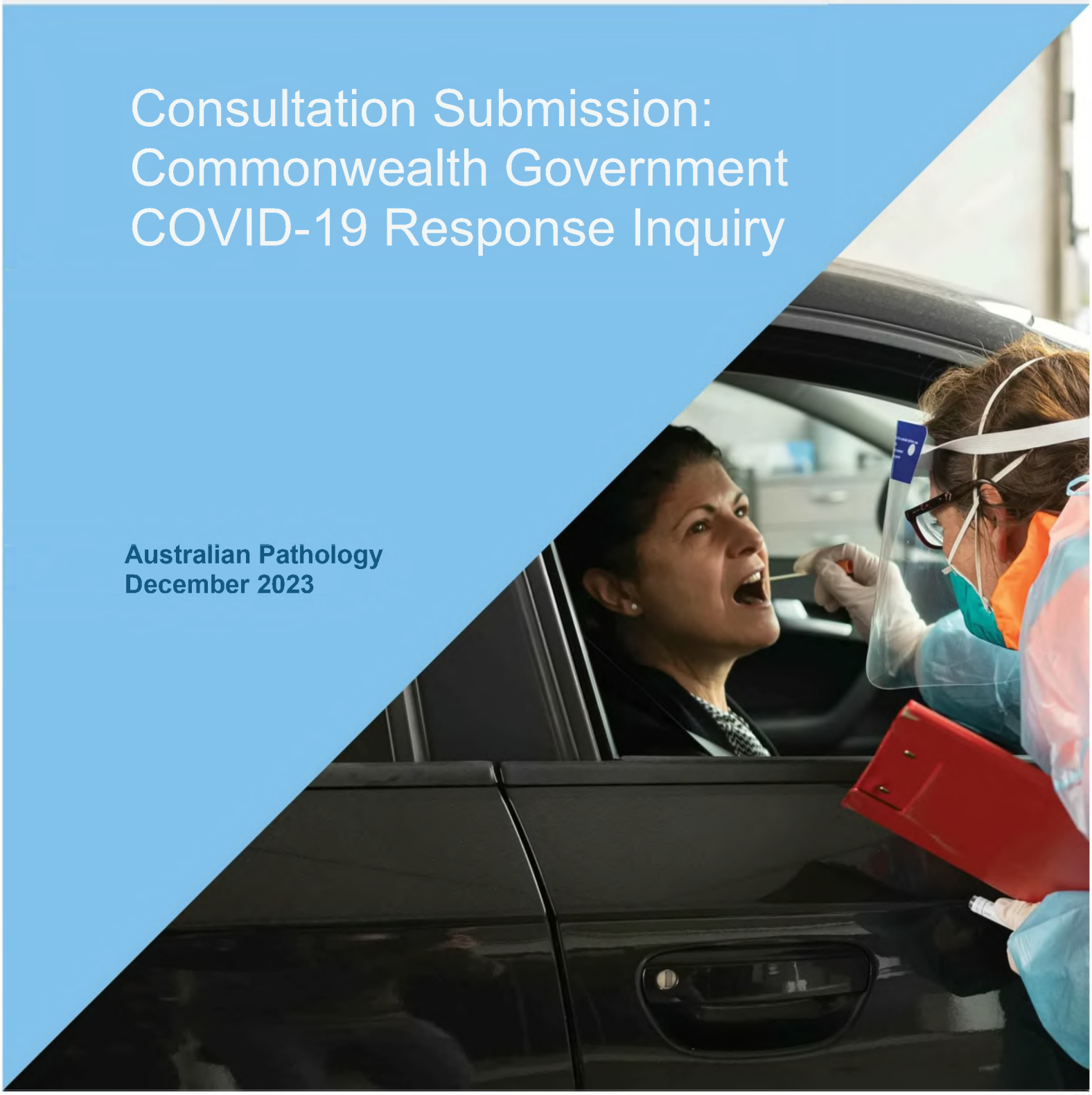
AUSTRALIAN Pathology

Representing private pathology in Australia

Consultation Submission: Commonwealth Government COVID-19 Response Inquiry



Australian Pathology
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About *Australian Pathology*

Australian Pathology is the peak body representing 95% of the private pathology providers in Australia. Our members include national companies such as Australian Clinical Labs, Healius and Sonic Healthcare, small boutique laboratories such as Histopath, and several IVF providers, such as Genea, Monash IVF and Virtus.

Our members provide 90% of all pathology services in the community and private hospitals and are exclusive providers under contract to a range of public hospitals and the National Defence services as well as providing national screening programs such as the National Cervical Screening Program, and the National Bowel Cancer Screening program. Our members support more than 900,000 patients with pathology testing per week and employ more than 35,000 people.

Australian Pathology welcomes the opportunity to respond to the *Commonwealth Government COVID-19 Response Inquiry*.

Our Role in Australia's COVID Response

The members of Australian Pathology were at the forefront of the public health response to the pandemic. The public health response across Australia was aimed at limiting the spread of the disease, to manage the risk of overloading the hospital system, until such time as a vaccine or other effective therapy was widely available. Accurate and timely diagnosis of COVID cases was essential to this approach. From the time the test first became available in April 2020, until the end of 2022, the Australian pathology sector collectively provided more than 75 million PCR tests. Since the end of 2022, COVID testing in the general community has all but ceased, with the small amount of ongoing testing in late 2023 almost exclusively being undertaken to protect the vulnerable aged care communities and immunocompromised hospital patients.

The response from Australian governments was effective at controlling case numbers and deaths, particularly in the period of greatest risk prior to the widespread availability of effective COVID vaccines. Achieving this outcome simply would not have been possible without the contribution made by the pathology sector in Australia. Australian Pathology's members invested in the necessary capital, equipment, and workforce, to be able to provide best-practice PCR testing at the scale needed to effectively monitor the most at-risk population groups across the entire country. Access to services was timely and equitable. The sector was innovative in the approaches it took to be able to scale up testing to maximum possible capacity and provide results to authorities, treating clinicians, and patients, as quickly as possible. When we consider that a diagnostic test for COVID-19 did not even exist in March 2020, for the pathology sector to be able to provide the service it did throughout the pandemic was nothing short of remarkable.

In April 2023, Deloitte completed a *Review of the impact of the Pathology Sector Response to the COVID-19 Pandemic*. A copy of this report is attached to this submission for reference.

Barriers to service provision

In the process of implementing a rapid and massive public health screening program, Australian Pathology's members faced a number of issues involving various levels of Australian governments which needed to be resolved before testing could be rolled out at scale to the Australian population. Broadly, these were practical issues relating to service provision, regulatory issues relating to service provision, and financing issues. In expanding on these issues below we shall attempt to illustrate some of the interlinkages which exist between them.

Practical issues

The main practical issues that pathology providers faced which touched on Commonwealth government responsibilities related to: access to personal protective equipment (PPE) and other testing-related consumables, and handling community expectations.

Consumables and the National Medical Stockpile

Australian pathology's members employ around 35,000 workers. During the peak of the pandemic, our members doubled the workforce of pathology collectors, the people on the front line collecting respiratory samples for PCR testing. As employers, our members have a duty of care to their employees and being able to supply adequate PPE to collectors as well as the laboratory staff who were handling samples was a significant supply problem for all of our members who were performing COVID tests, especially during the period April – September 2020.

The National Medical Stockpile (NMS) is intended to be maintained by the Commonwealth Government Department of Health for use in response to a national health emergency, such as the COVID pandemic in 2020. PPE are some of the items that are supposed to be available from the NMS; this was one of the recommendations made in the reviews which followed the 2009 Swine Flu pandemic. In spite of the existence of the NMS and the learnings from our experiences in 2009, our members' experience was that they were not able to rely on the NMS to provide any significant quantities of PPE.

Instead, our members filled their PPE requirements by leveraging their existing relationships with global suppliers. Because of the global nature of the COVID pandemic, there was significant competition for the limited supply of PPE (as well as other key consumables, such as PCR reagent) which caused the prices of these commodities to increase dramatically. In an extreme example, there were some suppliers charging several dollars each for face masks which were previously available for a few cents each – markups in the order of 50 – 100 times the pre-pandemic prices – simply due to the high level of competition for such items in the early stages of the pandemic.

A properly stocked and managed NMS could have ameliorated the pressure on medical providers, who, in 2020, were instead forced to purchase PPE supplies at grossly inflated prices. We note that some items have limited shelf lives, meaning that it may not be practical to maintain a physical stockpile; in such cases the government should engage suppliers (perhaps on retainer basis) to ensure that the suppliers can ramp up production and supply to Australian buyers (whether the government or end users) at short notice.

Community expectations of "free" testing

Another practical issue which our members had to deal with arising from the Government's handling of the pandemic was a public expectation that testing would be "free". Australian Pathology's members completely support the public health messaging which was encourage Australians to test early and test often. Australian Pathology's members also completely support the messaging that Australians should not need to fear having to pay for community screening tests if they were symptomatic or had been exposed to a COVID-positive person. However, we note that there were several exceptions to the "free testing" that were not adequately communicated to the public: travel-related testing, and workplace-related testing.

At various times throughout the pandemic, Australian state/territory as well as international governments required a negative COVID test result prior to travel and it was neither intended nor appropriate for the government to fund such testing. Unfortunately, the overarching messaging about "free testing" – while correct from a public health perspective – likely meant that some individuals accessed a government-funded community screening test for travel purposes, which might be considered either inappropriate or non-compliant claiming within the context of a Medicare claims audit.

Later in the pandemic, there was a patchwork of regulatory requirements surrounding the nature of "proof of test" for travellers depending on the jurisdiction to which they were travelling. The government-developed digital vaccination certificates to allow check-in at public venues and interstate/international travel later in the pandemic were an outstanding example of what might be possible in future for sharing of test results or other 'proof of service' requirements, and having a single government-sponsored portal or app makes things easier for both providers and consumers, and early action to put the framework needed to support a similar system for future pandemics might be warranted. Prior to this being developed, service providers had to try and accommodate requests from consumers to provide proof of testing in the format demanded by the travellers' destination. This placed unnecessary administrative burdens on providers, who were already having to manage a multitude of service-related issues. Ideally, governments (both intra-national and international) would work together to agree on a single documentation standard. This would streamline the administrative process for providers as well as making the process of establishing health status easier for consumers.

Particularly during the 'opening up' phases of the pandemic, some workplaces required regular COVID testing to manage the risk of cross infection within the workplace. This was important for workplaces dealing with high-risk groups such as hospitals or aged care facilities, but it was not limited to such workplaces. It was not entirely clear whether the Government intended for this type of testing to be included in the scope of services that it was funding, even though there would be strong public health arguments to support it. Demand for workplace was partly driven by government regulations as well as individual employer COVID policies. We would point out that some of these policies would have in turn have been based on advice or regulations published by the Commonwealth or state/territory governments.

In future, it would be helpful if the language used by government to describe publicly funded services is not "free" but instead, "paid for by the government", or "covered by Medicare", or similar, making it clear that the patient will face no out-of-pocket, but that there still is a cost to provide testing. While this might seem a trivial distinction to draw, medical services are not costless to deliver and it would certainly assist providers to manage those situations when the consumer is requesting a service that the public funding was not intended to cover.

Use of Rapid Antigen test kits

Rapid antigen tests (RATs) played an important complementary role to PCR testing. In particular, widespread use of RATs was useful for managing limited PCR testing volumes during peaks in demand. However, there was limited public understanding of the limitations of RATs and this likely resulted in sub-optimal public health outcomes arising from RAT use. Most importantly, public health communication did not make adequately clear that RATs are complements to PCR testing, and not a substitute.

The fact that RAT testing is generally less sensitive than PCR tests means that they may not detect the virus in individuals with lower viral loads, especially in the early stages of infection or in asymptomatic carriers. This likely means that negative results from RATs undoubtedly gave some infected individuals a false sense of security, leading to mass-spreader events, which could have been avoided if a PCR test had been used and detected the infection. In addition, the lower sensitivity of RAT testing means that it should not be relied on as a screening tool for those working in sensitive settings, such as hospitals.

The ideal deployment of PCR tests and RATs involves a strategic balance from a public health policy design perspective. Ensuring that the community correctly utilises both testing methods requires some nuanced communication from public health officials, which in turn relies on a degree of health literacy amongst the community. Increasing awareness and understanding of pathology testing as well as key epidemiological concepts such as test sensitivity/specificity, and false positive and false negative results, would make the government more capable of delivering more nuanced public health policies in future.

Regulatory issues

The Medicare rules are designed to protect benefit integrity and service quality and under normal circumstances, the regulation's lack of flexibility and outdated nature, while cumbersome, does not present a significant impediment to service provision. However, as the early stages of the COVID pandemic emerged, the Medicare regulations presented service providers with a series of regulatory obstacles which added complexity to and retarded the pathology sector's ability to move quickly in response to the rapidly evolving public health situation.

Drive-thru testing quickly became the preferred method for the pathology sector to be able to provide efficient mass testing. It allowed for patients to remain separated, limiting cross-infection which would have occurred in traditional waiting rooms. It also afforded the pathology collectors an element of environmental protection by creating a greater degree of physical separation than would be afforded in an ordinary medical attendance room typical of pathology collection centres. Providing drive-thru testing was not without its challenges: site logistics (especially how to place collection infrastructure), as well as traffic management, were new workplace puzzles that pathology providers had to solve 'on the fly' in order to operate drive-thru facilities, and no two sites were exactly the same.

While drive-thru testing should probably be a preferred method for providing screening tests in any future respiratory pandemic, the existing Medicare rules for pathology testing are quite restrictive in where and by whom a sample can be collected. There are some good quality-related reasons underpinning some of these restrictions but the regulation does not have any "catch-all" provisions to cover any unusual or exceptional circumstances. The Medicare compliance team at the Department of Health ultimately took a pragmatic approach to pandemic testing, but this was not a consistent approach, with some of the initial compliance communications from the Department of Health taking a far harsher tone towards providers. It would be far better if providers simply did not have to worry about the possibility of being penalised for non-compliance when taking actions expedient to a public health emergency response.

Financing issues

Pathology providers in Australia faced unprecedented challenges during the COVID-19 pandemic not least of which related to financial management. The early stages of the pandemic created a financial 'perfect storm' for pathology providers. The costs associated with sourcing the PCR testing reagents and PPE were increasing exponentially, and providers needed to grow their work force to adequately staff sudden increase in testing and collection efforts. At the same time, business cash flow dried up due to the cancellation of many other medical services.

The financing arrangements to pay for community COVID screening tests were not made explicit at the outset, with the focus and effort of policymakers and providers alike being on rolling out high-volume testing as quickly and efficiently as possible. The public health messaging strongly implied that screening tests would be covered by Medicare, but under the Medicare rules, screening tests are not covered unless the Medicare item is explicitly for screening purposes. In addition, the Medicare rebate for item 69494 (which was the most appropriate existing item under which a new COVID test could be billed) was inadequate to allow providers to meet costs and would have resulted in mass bankruptcy of providers had the government not acted quickly to put in place the temporary Medicare items that it did.

However, during the latter part of 2020 and into 2021, it became clear that the Commonwealth government was not willing to continue to bear the sole financial burden of paying for COVID screening tests, particularly when the state governments had jurisdictional control over some of the circumstances under which communities could be tested. The Commonwealth reminded providers in a series of Medicare compliance-themed letters that community screening tests should be directed to state health departments for payment. While technically correct from a regulatory and compliance standpoint, seeking payment from state governments presented a new series of challenges to providers. While the Medicare claiming channel is established and well-understood, seeking payments from state governments for high volumes of patient tests was neither straightforward nor consistent across jurisdictions. Australian state and territory governments were not resourced or equipped to handle the types of invoices that Medicare routinely deals with, and this led to payment delays. The various state governments also each had their own documentation requirements of providers, which again created additional administrative barriers to service provision. It would have been far preferable for providers to simply be able to utilise the existing Medicare billing channel and for the multiple levels of government to negotiate within the COAG structures the financial reconciliation associated with the costs of community screening tests. It is unacceptable that multiple levels of government should each be directing medical services providers to bill the other level of government for services provided during a pandemic and such a situation must be avoided in future.

Compounding the cash flow and financial challenges was the ill-advised requirement placed on pathology providers to bulk bill COVID screening tests. While the public health intention was one which the pathology sector supported wholeheartedly – that individuals should not hesitate to seek testing out of fear of having to pay out-of-pocket medical fees – the government's chosen method of implementing this proved problematic. The bulk billing clause written in to the COVID item descriptor gave private health insurers an excuse to refuse payment to pathology providers for COVID testing performed on hospital inpatients. This was not the intent of the regulation but it created disagreement between pathology providers and private health insurers, and significant administrative issues following on from the bulk-bill clause in the item descriptor.

In addition, it is not clear that including a bulk-billing requirement in a Medicare item descriptor is even lawful. Health services in Australia are not nationalised and therefore the government has no price-setting powers. Medical service providers in Australia are free to choose whether or not they are willing to bulk bill. Medicare benefits in Australia are a payment to eligible persons (not Medical providers), intended to help cover the cost of eligible medical services. A medical provider may choose to accept the Medicare benefit as full payment for their services, but this is a choice that a provider makes. A Medicare-eligible patient's benefit should never be made contingent on a medical provider's billing decision.

In summary, pathology providers found themselves caught in the crossfire of conflicting expectations, financial uncertainties, and rising costs. The lessons learned from these challenges underscore the need for a coordinated and harmonised approach between the various levels of government in financing any future pandemic response.

Recommendations

1. Strengthen the National Medical Stockpile (NMS):

Maintain a robust and well-managed National Medical Stockpile to ensure an adequate and timely supply of personal protective equipment (PPE) and testing consumables during public health emergencies. This would prevent pathology providers from relying solely on global suppliers, especially during periods of heightened demand and increased prices.

2. Add Flexibility to Medicare Regulations:

Enhance the flexibility of Medicare regulations to accommodate exceptional circumstances, such as drive-thru testing during public health emergencies. Add a catch-all provision to cover the entire Medicare schedule for public health emergencies, ensuring that providers can respond promptly without the fear of penalties for non-compliance.

3. Coordinated Financial arrangements:

Establish a coordinated financing framework between the Commonwealth and state governments to avoid confusion and delays in payments. Streamline the billing process through existing Medicare channels and negotiate financial reconciliation within established COAG structures, preventing providers from dealing with multiple levels of government for payment during a pandemic.

4. Clear Communication on Testing Costs:

Ensure that public communication during any future pandemic clearly conveys that while testing may be funded by the government or covered by Medicare, it is not entirely "free." Use language such as "paid for by the government" to emphasise the financial aspect and avoid misunderstandings, particularly regarding exceptions to free testing, such as travel-related or workplace-related testing.

5. Establish clear parameters for Travel and Work-related Testing:

Clearly define the scope of publicly funded workplace testing, avoiding potential discrepancies and ensuring alignment with broader public health goals. Develop a unified approach to hospital and travel-related testing requirements to streamline processes and eliminate confusion. Establish standardised documentation requirements for travel-related and workplace-related testing to reduce administrative burdens on medical providers. This could include a government sponsored portal or app to streamline proof of testing requirements, ensuring consistency across jurisdictions and simplifying the process for both providers and consumers.

6. Long-term Planning for Future Pandemics:

Learn from the challenges faced during the COVID-19 pandemic and engage in long-term planning for future pandemics. This includes refining financing arrangements, enhancing stockpiles, and establishing clear communication channels to ensure a more coordinated and effective response by all stakeholders involved in the healthcare sector.

Implementing these recommendations will contribute to a more resilient and responsive healthcare system, better prepared to handle the challenges posed by future pandemics.

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