



Submission to the Senate Community Affairs Legislation Committee

Health Legislation Amendment (Modernising My
Health Record—Sharing by Default) Bill 2024

JANUARY 2025



Executive Summary

Australian Pathology suggests that the Senate Committee consider delaying passage of legislation until:

- the Department of Health has consulted with all stakeholders in the health sector, given that the legislation potentially applies to every health care provider in Australia. Many providers will not yet have considered the possibility that they might one day be forced to upload patient data to My Health Record, and likely have no concept of what might be involved in compliance; and
- the intended scope of implementation is broad enough to meaningfully improve the breadth and accuracy of data being uploaded to My Health Record. Pathology and Diagnostic imaging providers are already leading the way with regards to both electronic access to results and uploading of information to My Health Record.

If the Bill is to be passed, we suggest that Senate Committee consider amending the Bill to:

- include a requirement for the **My Health Records Rules** to be subject to a regular and independent statutory review, which should include consultation with included clinical groups on the effectiveness and appropriateness of the **My Health Records Rules**;
- include a requirement that significant additions or alterations to the **My Health Records Rules** should be reviewed for appropriateness within twelve months of being introduced;
- remove the civil penalties, or limit them to instances of intentional and malicious withholding of patient information, in given that there are other more reliable and more complete sources of patient information than the My Health Record at the present time;
- indemnify providers against any breaches of patient privacy that result from the uploading of patient information undertaken to comply with this legislation; and
- not come into force until 2026 at the earliest, to allow for proper consultation on the detail of clinical exclusions and other technical aspects of the systems implementation.

Background

Australian Pathology welcomes the opportunity to provide a submission to the Senate Community Affairs Legislation Committee regarding the *Health Legislation Amendment (Modernising My Health Record—Sharing by Default) Bill 2024 (the Bill)*. Australian Pathology provides the following comments relevant to this Bill for the Senate Committee's consideration.

Limited consultation and compressed timeframes to respond

Australian Pathology did not receive this bill until it was tabled in Parliament on 21 November. This has given us very limited time to understand the scope of the proposed legislation and insufficient time to seek formal legal advice on the possible business implications should this bill be passed. Even though Australian Pathology has been engaged in discussions with the Department of Health on the broader issue of uploading of patient records since late 2023, there are a number of significant aspects of the that the department has not raised in discussions with us, specifically:

- civil penalties (the amendments to sections 76A, 78A, 78C, 78D of the *My Health Records Act* and section 19AF of the *Health Insurance Act*)
- the requirement for businesses that cannot upload to My Health Record to display notices (78D of the *My Health Records Act*)
- the provisions to recover Medicare benefits from providers (the amendments to section 19 of the *Health Insurance Act*, especially section 19AG)
- the additional record keeping requirements for upload exemptions, which are likely to incur a significant additional regulatory burden (section 78C)

Pathology providers in Australia are already improving digital access to patient information

Australian Pathology's members have been generally supportive of advances in technology that serve to improve the health and wellbeing of patients. To this end, over the past decade our members have of their own volition developed systems which provide electronic access to test results as soon as they are available. Clinicians all over Australia routinely receive the results from tests they requested for their patients directly from the pathology provider. These systems are safe and secure and ensure that the requesting clinician has the diagnostic information relevant to their patient as soon as it is available, while also protecting patient privacy by ensuring that their sensitive health information is not accessible to others. Our members have been engaged for more than a decade with practice management software providers such as Best Practice and Genie to develop ways of securely passing patient information between requesting clinicians and the laboratory.

Our members have been engaged in these kinds of activities at their own expense, because they serve to improve the clinical outcomes for patients as well as making life easier for treating clinicians, such as GPs, allowing them to focus on providing the health care needed by the patient.

Sometimes there are good reasons for why it might not be appropriate or possible to share patient information:

- Concerns relating to clinical appropriateness or safety of the information
- Concerns relating to patient privacy

- Patients who have chosen to ‘opt out’ of having their data handled in this way

These reasons are transferable to, and apply to, any upload of patient data to My Health Record.

Australian Pathology’s members have generally been very supportive of initiatives to improve the interconnectedness of health information systems, noting that matters of patient privacy, clinical sovereignty, and clinical safety should not be compromised. We note that Australian Pathology and its members have been engaged participants in the Department of Health’s various digital health working groups.

Uploading data is a technology service, not a health service

We urge that the Senate Committee note that **digital handling of patient data, including uploading to third party systems, where the organisation uploading the data is not responsible for data security and cyber governance, is not the core business for health care providers**. Health care services are primarily about providing patient care. Uploading of data to My Health Record, or any other health data repository, is fundamentally a technology service. Yet this legislation would make health businesses responsible for delivering this technology service, and potentially liable for penalties should that technology service fail to comply with the legislation.

Pathology and other health care providers cannot be expected to have any of the necessary technical infrastructure, expertise, or resources to upgrade their IT systems to be able to comply with these requirements should they be introduced. Health care providers should be primarily concerned with treatment and diagnosis of their patients, not IT systems upgrades.

A fundamental pre-condition for the majority of patient records being uploaded to My Health Record is that health providers be able to comply with such a requirement. This is not simply a matter of mandate; it is about whether or not the infrastructure (especially cyber security and governance), resources, and capabilities exist for health care providers to meet the proposed obligations.

The fact is that, at present, there will be a significant proportion of health care businesses who will not be able to easily comply with a compulsory upload requirement. Given that the Bill currently includes significant financial and regulatory penalties for non-compliance, it creates the potential for a fundamentally uneven playing field, dividing the health sector into providers that are easily able to comply and those that are not. It is likely that smaller providers, who are almost certainly going to be reliant on third-party (and often international) software developers, will have the least control over their businesses’ ability to comply with this proposed legislation.

Compliance will incur significant costs for providers

The **upgrading of business computer systems to comply with the proposed legislation will not be costless**. Even though the Australian Digital Health Agency has developed some middleware that might be of some use for some businesses with the necessary technology upgrades, this is not by itself sufficient support that would enable any business to become capable of uploading patient data. Providers will either need to engage software developers to upgrade their existing practice management software, or change to using a software package that has the necessary capabilities. There has been no indication that the government will provide any financial support to assist businesses to meet these costs.

In spite of this, it is clear from previous policies that the Government does understand that uploading records to My Health Record imposes a cost on medical practitioners. General practices uploading to My Health Record have been eligible for eHealth incentive payments (which are calculated on a standardised per-patient basis) since 2016. It is inequitable for the government to continue to make payments to other medical providers to help meet the cost of uploading records to My Health Record, while expecting other health care providers to simply meet these costs with no compensation.

Scope of the Bill

Passage of legislation should be delayed until the Department of Health has consulted with all stakeholders in the health sector, to give all health professional an understanding of what is going to be involved in complying with this legislation when it does apply to them in future. Many health care providers in Australia are small businesses with limited ability to implement the necessary systems changes to comply with any requirement to upload patient information to My Health Record, and most of these providers will not yet have considered that one day they could face obligations that have civil penalties attached in this regard.

My Health Record has not been widely adopted by health professionals in Australia as a reliable data source. This lack of trust stems from the system's incomplete and often inaccurate data, which limits its utility in clinical decision-making. While the idea of a national digital health record is commendable, the current state of My Health Record fails to meet the necessary standards of reliability, completeness, and accuracy that health professionals require for effective patient care.

We understand that the Bill is intended to give effect to recommendations made by the government's Strengthening Medicare Taskforce. The reasoning underlying the taskforce's recommendation to make uploading to My Health Record compulsory was: for My Health Record to be a useful clinical data source, the patient data needs to be as complete as possible; therefore, to help ensure the completeness of data in My Health Record, we should compel the upload of all patient information by all health providers. Unfortunately, what the government is proposing at present falls short of addressing this recommendation. While the bill is broad enough to apply to all health providers, Minister Butler's second reading speech only mentions pathology and diagnostic imaging providers, and there is no timeline or plan for when other health professionals, such as general practitioners or specialists, will be subject to similar uploading requirements.

In addition, the proposed legislation would devolve significant powers to The Department of Health via the creation and management of the **My Health Records Rules**. Based on our recent experiences with some parts of the Department, we have serious concerns about the Department of Health's ability to effectively implement the rules in a way that aligns with clinical practice and delivers the intended outcomes for both the government and patients. We are concerned that the department lacks the necessary expertise and understanding of the delivery of clinical care in Australia by healthcare providers, particularly pathology services. Appropriate implementation of this policy requires not only technical knowledge but also an in-depth understanding of clinical workflows, patient care needs, and the broader healthcare system as a whole. We do not believe that the Department has the capability to develop and enforce regulations that will be both workable and beneficial in practice and consider that there is a real risk that the proposed rules will not achieve the intended outcomes, creating significant regulatory burden with no benefit to patients.

In light of this, we **urge the Senate Committee to consider amending the bill to ensure that implementation of the My Health Records Rules must be informed by a group that has the necessary clinical and operational expertise from a broad base of clinical users**, including pathology and radiology providers as the first specialty medical groups to be compelled to upload data under this draft legislation.

The My Health Record is based on a flawed and outdated digital health model

The fact is that at present, My Health Record is not utilised by health professionals in Australia as a data source because it is not complete or reliable. Imposing a requirement solely on pathology and diagnostic imaging providers will not by itself address this fundamental problem with My Health Record, and even if the compulsory upload requirement were extended to all health providers in the short term, it will take a number of years before the data set available in My Health Record is complete enough to be useful.

Given the pre-existing limitations and the timeframes involved in rectifying them, it is unsurprising that other countries that have had more success in improving their citizens' access to their own health information have achieved this by adopting information sharing models that eschew centralised databases (like My Health Record). **Centralised databases create significant privacy risks and are a target for cyber criminals**, and as such are considered by some experts to be an outdated approach to what is in essence a data sharing problem. A more modern approach that has had success in other countries has involved secure methods of accessing patient information held in the locations where such records already exist, with the holders of that information providing a method for patients and other registered and appropriate users of that information to access it.

In addition, Australian Pathology notes that our members' current experience with uploading patient records has been that, due to technical limitations and in spite of their best efforts, not every patient can be matched to an Individual Health Identifier, meaning 100% upload of results will never be possible. Paper pathology requests present significant additional administrative issues. Australian Pathology suggests that the Senate Committee amend the bill so that providers should not face any financial or civil penalty for failing to upload patient records unless the pathology request was also received electronically.

Not all patient information should be shared

We would note that ownership of medical records have historically been considered the property of the treating clinician, and giving patients unfiltered access these via My Health Record potentially raises issues relating to clinical care. While it is true that some patients are well informed and might make appropriate judgements based on their test results, this will not universally be the case.

Pathology reports are written using technical medical language which patients could misinterpret. Even quantitative test results can vary based on the platform and testing methodology, creating the risk that patients could make poor health decisions based on their own reading of the numbers, rather than consulting with their treating practitioner for proper medical follow up. At an absolute minimum, it must be clear to patients that pathology test reports and results (which are written with the treating clinician as the primary audience) do not constitute medical advice; it is the patient's GP or specialist who needs to provide them the medical advice for the patient to be able to make a properly informed decision about their health care. Simply providing access to diagnostic test results in the absence of trained medical advice risks patients making poorly informed decisions. There may be a longer-term shift involving improving health literacy which would reduce the risks of misinterpretation, but at the current time Australian Pathology cannot support what the government is proposing in

this legislation.

Australian Pathology notes that the government introduced a 7-day delay policy, to address industry concerns around clinical safety associated with uploading of medical records. Even when it is appropriate to share information with patients, it is not often necessary for that information to be shared with them (as opposed to their treating clinician) urgently. We suggest that the Senate Committee consider amending the legislation to include a delay by default, with lowering or removal of such delays to patients accessing pathology records be considered on a test-by-test basis in consultation with clinical practitioners.

Privacy concerns

The government must clarify how it proposes the health sector as a whole should manage privacy-related concerns and a patient's right to opt out from My Health Record. Australian Pathology's position is that pathology providers cannot be held responsible for any failure to comply with a patient's "opt out" request. Given that pathology providers have no direct interaction with the patient in a significant proportion of cases, the responsibility for correctly administering patients' "opt out" status must lie either with the pathology requestor, or with the government's patient data system itself.

The act of uploading patient information is a use of patient information that would not have been envisaged when the *Privacy Act* was passed in 1988. The Senate Committee should consider amending the bill to indemnify health providers who are uploading patient data to My Health Record to comply with these new requirements against prosecution for any consequential breaches of the Privacy Act.

Summary

Australian Pathology considers the Bill that is before the parliament has some flaws that can be resolved. We are concerned that it would make health care providers responsible for providing what is fundamentally not a health care service as they exist in Australia today. We do not consider this appropriate or good public policy at the current time, given the state of existing medical information systems, and the current clinical practice of medicine in Australia.

The Bill is intended to give effect to recommendations made by the government's Strengthening Medicare Taskforce. However, the Bill is unlikely to achieve its goal of ensuring that patients and clinicians have better access to patient data, because:

- My Health Record is not a complete record, and as such is not a trusted source of information for clinicians. There are already numerous other clinical information systems operating outside of My Health Record, which clinicians do trust (and therefore utilise).
- The government's stated intention is to target pathology and diagnostic imaging providers first, but the government has provided no timetable for when other health and allied health professions will have similar requirements placed upon them. For patient information in My Health Record to be clinically useful in the way envisaged by the Strengthening Medicare Taskforce, it will be necessary for all providers to be uploading relevant patient information, not just diagnostic service providers.
- Pathology data is already made readily available to clinicians, and patients in some circumstances, using systems outside of My Health Record, thanks to initiatives undertaken by pathology providers over recent years.

The government has stated that it intends pathology and diagnostic imaging providers to be the first targets of the new legislation – while simultaneously acknowledging that many pathology and diagnostic imaging providers are already doing uploading a significant proportion of the relevant patient data. Meanwhile, there is no timetable or plan for when these requirements will be imposed on other health care providers, even though the participation of all providers in the health care system in Australia will be needed to achieve the stated goal of ‘empowering patients’ to ‘take charge of their own health and wellbeing’ under the envisaged model of usage for My Health Record.

As already explained, Australian Pathology’s members are supportive of these kinds of information sharing initiatives, as demonstrated by actions that they have taken over many years and at considerable expense to their businesses. In light of this, and the fact that data sharing is not yet considered a fundamental and integrated part of delivering health services, we do not consider it fair or reasonable to impose civil penalties for businesses that are not already sharing patient information.

The government’s stated intentions at present are limited to pathology and diagnostic imaging providers and therefore unfairly singles out the sector already identified as being the ‘best practitioner’ in this regard, to be subject to legislated penalties.

Compulsory uploading of pathology results raises significant administrative challenges to providers, which the government has not addressed. These include privacy-related concerns, and other technical challenges. In addition, there will be significant costs associated with the regulatory compliance involved should the Bill be passed in its current form. In the absence of any financial assistance from the government, these costs will inevitably need to be passed on to patients, even though this policy is unlikely to significantly improve clinician or patient access to pathology results, given that most pathology results are already routinely being provided electronically via other channels than My Health Record.

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 Monash IVF and Virtus.

We 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.

Over 99% of out of hospital pathology services are bulk billed, higher than any other specialty. We provide national screening programs such as the cervical cancer screening program for HPV testing, and the National Bowel Cancer Screening program.

We support more than 1,000,000 patients with pathology testing per week and employ more than 35,000 people. Every single (100% of all) Cancer and some 70% of all medical decisions are dependent on a diagnosis from a Pathologist delivered by a pathology laboratory. If you have ever had a blood test, biopsy or a swab, you have received services from a Pathologist, which are delivered in a pathology laboratory.



Australian Pathology

Level 1, 16 Napier Close
Deakin ACT 2600

P: 02 6282 2277

E: info@australianpathology.com

www.australianpathology.com

Representing
private pathology
in Australia