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

(November) 2024

Office of Impact Analysis reference: OIA23-05874



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About this Impact Analysis

Any policy proposal or action of the Australian Government, with an expectation of compliance, that would result in a more than minor change in behaviour or impact for people, businesses or community organisations must be accompanied by an Impact Analysis.

This Impact Analysis concerns the Health Legislation Amendment (Modernising My Health Record—Sharing by Default) Bill. For an overview of the issue, the executive summary and initial chapters provide a concise foundation. For a more detailed exploration, readers can focus on the sections covering the seven key questions for an in-depth discussion.

Executive summary

Australia's My Health Record

In 2012, Australia introduced the Personally Controlled Electronic Health Record – now known as My Health Record – as a national consumer-controlled electronic health record system. As of August 2024, more than 24 million Australians have a My Health Record (ADHA 2024).



My Health Record contains key health information like immunisations, pathology and diagnostic imaging reports, prescription and dispensing information, hospital discharge summaries and other key health information all in one safe and secure system. My Health Record can support diagnosis and treatment, document treatment approaches and results, and promote continuity of care for consumers, including during an emergency.

In 2016, the Australian Digital Health Agency was established by the Australian Government and became the System Operator for the My Health Record system.

The policy problem

The Australian health system is complex with more than 1.1 million individual healthcare providers in public and private services, delivering health services to almost 27 million Australians (Services Australia 2024). Currently, the way a consumer's health information is collected and stored is fragmented across thousands of clinical information systems used by healthcare providers. In most cases these systems do not enable the health information to be shared with consumers or with other clinical information systems.

The introduction of the My Health Record system 12 years ago was intended to alleviate this complex problem. My Health Record is designed to give Australians easy access to their key health information. However, the continued voluntary participation of healthcare providers to upload to My Health Record means not all key health information is currently shared to a consumer's My Health Record.

As a result, consumers are still struggling to access their health information, and this impacts their ability to participate in their own healthcare and make informed decisions about their health journey. It also means they experience unnecessary and often costly duplicate tests and follow up appointments which can delay treatment and lead to poorer health outcomes.

Healthcare providers are also frustrated due to a lack of a consistent access to health information to support their clinical decision making and care coordination for their patients. Pathology and diagnostic imaging reports are one important piece of health information to support healthcare providers clinical decision making. Currently however, pathology and diagnostic imaging service providers are only sharing around half of pathology reports and one in three diagnostic imaging reports.

Consumers have expressed that they are largely happy to share their health information but are disappointed that My Health Record is not delivering this promise. They want their healthcare providers to upload their health information to My Health Record and use it when they receive healthcare across the health system. Consumers are becoming increasingly frustrated at consistently having to repeat their medical history despite the expansion in digital health (Consumer Health Forum of Australia 2021).

The policy response

This Policy Impact Analysis considers options to change the model of sharing diagnostic and pathology reports to a consumer's My Health Record from voluntary to mandatory (by default). This Impact Analysis considers the following two options to achieve this objective:

Option 1: create a legislative requirement on prescribed healthcare providers to share key health information to consumers' My Health Record unless exempted.

Option 2: maintain the status quo.

Focusing on two options represents the most beneficial approach to address this policy problem as it provides the opportunity for a clear comparison for evaluation. This approach also acknowledges that historic attempts to improve access to consumer health information through other options, including voluntary methods, has not achieved the significant and consistent outcomes required.

'Consumers will be able to trust the system, access their information at all times, and won't have to repeat their medical history every time they see a clinician'

Minister for Health and Aged Care, The Hon Mark Butler (Butler 2024)

Selecting the preferred policy option

Selection of the preferred option was established through consideration of comprehensive stakeholder feedback, regulatory impacts, and cost and benefit analysis for consumers, including vulnerable and Aboriginal and Torres Strait Islander populations, healthcare providers, pathology and diagnostic imaging providers and all Australian governments.

Option 1 provides the most effective solution, addressing current gaps and improving access to health information for both consumers and healthcare providers.

Option 2 fails to address the current incomplete access to health information experienced by both consumers and their healthcare providers.

This Policy Impact Analysis has been developed by the Department of Health and Aged Care (the department) in accordance with The Australian Government Guide to Policy Impact Analysis and in consultation with the Office of Impact Analysis. It will be used to inform the Australian Government regarding the decision to require healthcare providers to upload key health information to My Health Record by default, commencing with pathology and diagnostic imaging providers.

The vision for digital health

Australia's health system is one of the best in the world. The health needs of Australians are changing and to ensure these new and different needs are being met, digital health is a key driver of a more connected and sustainable health system.

Australians want the choice to be more involved in their own healthcare. They also want healthcare services to be more person-centred and for their medical records to be complete, understood, and accessible to them and their treating healthcare team no matter where care is being provided. To realise this objective, Australians understand that their health system must modernise and leverage digital health capabilities, services and tools that are user friendly, safe, secure and integrated.

Strategic alignment

The <u>Digital Health Blueprint 2023 – 2033</u> is the Australian Government's 10-year roadmap that outlines a vision for the role that digital health capabilities will play in delivering a more tailored, integrated, efficient and contemporary health system. The Blueprint details how digital and data reforms are designed to:

- ensure health information follows patients through the health system, so they can actively participate in, and make informed decisions about, their care
- enable our world-class healthcare professionals to access a joined up, real-time view of their patients' health information at the point of care, and
- ensure our health system becomes a learning health system able to safely and securely reuse health data to be more responsive to emerging technologies, and able to better use health data to plan for the future and inform public health needs (DHAC 2023).

'Digital health technologies will empower patients to monitor and take charge of their health and wellbeing, so they can interact confidently with healthcare providers and build their health literacy. This reform is one part of the overall strategy the government has — to put patients at the heart of a better connected and more personalised health system.'

Minister for Health and Aged Care, The Hon Mark Butler (Butler 2023b)

Modernising My Health Record

Australia's My Health Record system is a safe and secure place for Australians to access their key health information and is a key tool that is supporting the realisation of the Australian Government's vision for digital health. My Health Record is one of the world's only consumer-controlled national health information systems.

A consumer's My Health Record includes key health information like immunisations, pathology and diagnostic reports, prescriptions and dispensing information, hospital discharge summaries and other health information. Consumers can view and update their personal information, add emergency contacts, set up email or SMS notifications, check their Medicare information or cancel their record at any time.

Authorised healthcare providers like doctors, pathologists, and pharmacists can upload and view a patient's health information including allergies, adverse events, e-referrals, goals of care documents, shared health summaries, specialist letters and more.

However, it remains voluntary for healthcare providers to upload health information to a consumer's My Health Record. In December 2022, the Australian Government's Strengthening Medicare Taskforce published its final report. A key recommendation of the Taskforce was to increase the consistency of health information flowing from healthcare providers to My Health Record.

"...modernise My Health Record to significantly increase the health information available to individuals and their healthcare professionals, including by requiring 'sharing by default' for private and public practitioners and services...' (DHAC 2022)

In the 2023-24 Budget, the Australian Government agreed to commence the modernisation of My Health Record, including changes that would make it a requirement for healthcare providers – beginning with public and private pathology and diagnostic imaging providers – to share their reports to My Health Record by default to empower patients and make it easier for healthcare providers to coordinate care and make more informed clinical decisions.

History of My Health Record

In 2009, the National Health and Hospitals Reform Commission recommended that by 2012 every Australian should have a personal electronic health record that will at all times be owned and controlled by them.

'The introduction of a person-controlled electronic health record for each Australian by 2012 is an important systemic opportunity to enable person-centred care, support informed consumer decision making, improve quality and safety of care, reduce waste and inefficiency, and improve continuity and health outcomes for patients.' (National Health and Hospitals Reform Commission 2009)

In July 2012, the My Health Record system, originally named the Personally Controlled Electronic Health Record system (PCEHR), commenced operation on a voluntary opt-in basis.

Since 2016, the Australian Digital Health Agency (the Agency) has been the System Operator for My Health Record. In addition to its legislative responsibilities under the *My Health Records Act 2012* (My Health Records Act), the Agency delivers a range of services to promote and support the active use of the My Health Record system by consumers and healthcare providers.

All participants in the My Health Record system must have a Healthcare Identifier to access My Health Record. Services Australia operates the Healthcare Identifier Service on behalf of the department. The Healthcare Identifier Service is a national system that assigns a unique 16-digit healthcare number to healthcare recipients (individuals), healthcare provider individuals and healthcare provider organisations. This allows electronic systems across the national health ecosystem to identify them correctly, and associate information with the right patient and provider at the point of care.

The *Healthcare Identifiers Act 2010* and the *Healthcare Identifiers Regulations 2020* set the framework and rules for the Healthcare Identifier Service. Changes to this framework aim to support connected care for all Australians, focusing on patient benefits at the centre of all reforms.

Review of My Health Record

In 2013, the Royle Review of the PCEHR system was conducted by Mr Richard Royle, Dr Steve Hambleton and Mr Andrew Walduck. The Royle Review made 38 recommendations, including renaming the system to My Health Record and transitioning to an opt-out system (Royle 2013).

The <u>Health Legislation Amendment (eHealth) Act 2015</u> gave effect to the change of name to My Health Record and provided for opt-out trials. In 2016, to support the transition to an opt-out system, the department commissioned four trial sites split into two opt-in and two opt-out sites across states and territories.

The trials found that there was strong evidence to support the stakeholder consensus that optout should be the participation model into the future.

In May 2017, the Australian Government announced that the My Health Record system would transition to an opt-out model. The Australian public were provided with a period to decide if they wanted to opt-out, from July 2018 to January 2019. This resulted in 90 percent of Australian's being registered for a My Health Record, and 10 percent deciding to opt-out of the system.

The My Health Record system continues to operate on an opt-out basis, and Australians can choose whether to have a record or to cancel their record at any time.

This proposed reform seeks to respond to the growing calls from consumers and healthcare providers to increase the amount of health information in My Health Record to deliver even greater benefits than those already being experienced.

To give patients even more choice, the *my health* app was released by the Agency in 2023. Health information in a consumer's My Health Record is now available to access on mobile devices through the *my health* app. This means consumers can truly access their health information anywhere, anytime.

The My Health Records Act also provides for access controls to be set by the record holder to determine who can access their record or access certain documents in their record. Consumers may also request at any time that health information not be uploaded to their record.

Making sharing of health information the 'default' approach

In Australia, significant effort and investment has been made to enable the safe and secure sharing of health information across healthcare settings through the My Health Record system. However, after 12 years of operation, the voluntary nature of sharing requirements for participating healthcare providers has meant only limited health information has flowed into the system. This continues to limit the usefulness of My Health Record.

Internationally, mandatory information sharing frameworks between healthcare providers and healthcare recipients have been established. Examples include the United States, Canada and the European Union. While each has taken different approaches, the objectives are largely the same - to require consumers' health information be shared to improve health outcomes for the individual and support a more effective and efficient health system.

In Australia, healthcare consumers' 'right to data' and right to control their data does not include the practical facilitation of sharing information. Instead, sharing relies on a case-by-case, timeconsuming manual request process. My Health Record provides a sharing platform based on an authorising framework with the technical capabilities to enable consumers to manage access to that information.

The Office of the Australian Information Commissioner regulates the privacy aspects of the My Health Record system and provides <u>guidance</u> to healthcare providers on making information available to consumers. The Royal Australian College of General Practitioners publishes <u>general advice</u> to practitioners on providing information. This guidance relates to responding to requests for information, how long it should take to respond, and reasonable charges for providing access to information only.

Purpose

This Policy Impact Analysis explores options to increase the sharing of key health information, commencing with pathology and diagnostic imaging reports, to My Health Record by default. The objective of this policy is for all pathology and diagnostic imaging reports to be sent to My Health Record routinely, by default, or 'as a rule' unless there are valid reasons for this to not occur, such as when patients request that certain health information not be uploaded.

'If a patient gets a diagnostic scan or pathology test, then those results should be uploaded. At the moment, this happens by exception, it is not the rule. I intend to make it the rule.'

Minister for Health and Aged Care, the Hon Mark Butler MP (Butler 2023b)

Pathology and diagnostic imaging reports provide key health information which support healthcare providers across the health system with their clinical decision making and the care provided to consumers. The goal of this policy is to empower consumers and enable choice of healthcare providers through having better access to pathology and diagnostic imaging reports and avoiding the need to repeat their medical history across their health and wellbeing journey.

Background

Who can access My Health Record

My Health Record can be accessed by consumers, people they trust as nominated representatives, and authorised representatives who are responsible for managing a consumer's record if they are unable to make decisions for themselves. Registered healthcare providers who are a part of a consumer's care team can access a consumer's record at the point of care including when providing care in emergency settings.

The My Health Records Act outlines controls and guidelines for access to consumers' health data, including:

- the role and functions of the Agency as the System Operator
- the registration framework for healthcare providers and other organisations to participate in the My Health Record system
- a privacy framework which states who can collect, use and disclose certain information in the My Health Record system and under what circumstances, and
- the direct provision of care to an individual.

Information in the My Health Record system cannot be used for defined employment or insurance purposes. Penalties apply for any improper collection, use or disclosure of information in the system. No changes to these rules are being proposed.

In addition, My Health Record data is not yet available for research and public health purposes. My Health Record data will only be made available to researchers and public health experts once the My Health Record modernisation program has been completed and research and public health governance arrangements have been established. However, consumers already have the ability to elect not to have their de-identified My Health Record data used for research or public health purposes, and (identified) health information may only be used for research or public health purposes with the consent of the consumer.

My Health Record security and privacy safeguards

My Health Record is monitored by the Cyber Security Centre within the Agency. Security processes limit access to My Health Record, with conformance requirements for healthcare provider software to support health information sharing to the system. All personnel involved with the administration of the system undergo security checks, including policy background checks, and Australian Government Security Vetting Agency checks for those accessing more sensitive information.

A range of technologies protect sensitive information in My Health Record, including firewalls to block unauthorised access, auditing to track access to records, anti-virus scanning of documents uploaded to records, and system monitoring to detect suspicious activity.

A consumers' own privacy controls offer further protection of their health information. This includes management of their entire health record or specific documents, including:

- the ability to request to not have health information shared to My Health Record
- setting notifications to see when registered healthcare providers have accessed their record or when certain health information is added to their record, and
- appointing an authorised representative (such as a family member) to view and manage their record.

Consumers can also add information themselves to their My Health Record by:

- adding a personal health summary or advance care planning information which healthcare providers can see, and
- adding personal health notes which are not accessible to healthcare providers.

Consumers can use privacy controls, including setting restricted access codes, which limits who can access their record or specific documents in their record. Consumers may permanently delete a document from their record or hide and restore a document within their record. Notification preferences can be set to remind consumers to review who has accessed their record and can be set to receive notifications when it is accessed.

Data security and privacy

My Health Record is operated by the Agency at the Government security classification of 'Protected'. The controls in Protected systems are designed in line with the <u>Australian</u> <u>Information Security Manual</u>, are tested on a regular basis, and are assured under an Information Security Registered Assessors Program (IRAP). All new connectivity and access to My Health Record is comprehensively risk-assessed as part of current processes. Based on the assurance work conducted to date by the Agency, My Health Record includes the required controls to support the additional volume of pathology and diagnostic imaging reports expected to be uploaded as a result of the share by default reform.

To further enhance data security, in September 2024 the Agency released a new security conformance profile that will apply to all clinical information systems connecting to My Health Record, including those used by pathology and diagnostic imaging providers. This new conformance profile has been designed to meet evolving cybersecurity threats and includes new mandatory requirements such as the adoption of multi-factor authentication.

How My Health Record is being used today

Increased use of My Health Record during the pandemic demonstrated its added value. Consumers, their carers and families were able to access key health information easily and securely when and where it suited them. Healthcare providers could also access a consumer's health information at the point of care. Consumer activity surged in January 2022 with 13.75 million views following the increase in COVID-19 case numbers from mid-December 2021. By the end of January 2022, overall consumer activity returned to a lower baseline of 5.54 million views, still above pre-COVID-19 levels. Consumer activity post COVID-19 continues to be driven by a desire to access their health information contained in pathology and diagnostic imaging reports.

The value of pathology and diagnostic imaging reports

Since the Australian Government's announcement to transition the My Health Record system to a 'sharing by default' system, a record number of healthcare providers have commenced sharing to My Health Record by default.

Over the 12 months from July 2023 to July 2024 the total number of pathology and diagnostic imaging reports shared with My Health Record increased by 33% and 35% respectively. Over 10 million pathology and almost 1 million diagnostic imaging reports are now being uploaded to My Health Record each month. Consumer views have also grown with a 25% increase for pathology reports and a 40% increase for diagnostic imaging reports between August 2023 to August 2024.

However, some large private providers have indicated that meeting new share by default requirements for uploading reports to My Health Record would not become their standard practice until a legal requirement to do so is established.

In late 2023, all state and territory health ministers agreed to support the requirements for public pathology and diagnostic imaging providers to upload pathology and diagnostic imaging reports to My Health Record by default. As of September 2024, it is estimated that most states and territories are now uploading more than 75% of all pathology and diagnostic imaging reports. The department is continuing to work with states and territories to overcome any local barriers and technical constraints.

For the sharing by default of health information such as pathology and diagnostic imaging reports to become normal practice, an approach that goes beyond voluntary participation is required.

"...patients should not have to rely on the goodwill or good management of private providers to be able to access their own health data."

Minister for Health and Aged Care, The Hon Mark Butler (Butler 2024)

Modernising My Health Record

Australian governments, the broader health sector and multiple key national reviews have recognised the critical role of digital health capabilities to shift Australia's health system towards patient-centred care models.

The Productivity Commission's report on the five-year <u>Productivity Inquiry: Advancing</u> <u>Prosperity</u>, identified the My Health Record system as the foundation for comprehensive health data sharing in Australia.

This recognises My Health Record as critical national infrastructure that can be leveraged and scaled to support the growing health information sharing agenda of all Australian governments and the health sector.

The <u>Strengthening Medicare Taskforce Report</u>, released in 2022, recommended modernising My Health Record to significantly increase health information available to consumers and their healthcare providers by:

- requiring 'sharing by default' for private and public practitioners and services, and
- making it easier for people and their healthcare teams to use at the point-of-care.

The Strengthening Medicare Taskforce Report highlighted that access to real time health information is a critical foundation for a modern and connected health system. My Health Record is the only system within Australia's federated health system with the ability to connect a consumer's key health information between healthcare providers and across care settings in both public and private health services, and across jurisdictional borders.

In response, the Australian Government has invested in foundational work which is already underway, including:

- National information and data standards: 'Sparked' developing and supporting the adoption of consistent data formats across clinical systems means that health information is recorded consistently and retains its meaning when exchanged. Funding of \$9.3 million was provided as part of the 2023-24 Budget to establish 'Sparked'. Sparked is a community-led approach that involves consumers, healthcare providers, software developers and all Australian governments. As at August 2024, Sparked has more than 800 participants shaping the future of Australia's health system.
- Identity management reviewing the *Healthcare Identifiers Act 2010* to enable broader use to support the safe and secure exchange of health information across a greater representation of the health, aged care, disability and support sectors.
- National Provider Directory a single directory containing all healthcare providers to underpin national connection and national data and information sharing. This will draw from existing data sets held by Services Australia, HealthDirect Australia and the Australian Health Practitioner Regulation Agency.

• Share by default – The Australian Government invested \$13.1 million in the 2023-24 Budget to introduce the requirement for healthcare providers to share key health information to My Health Record by default, beginning with the pathology and diagnostic imaging sectors. Additional investment of \$0.8 million in the 2024-25 Budget was provided to the Agency to support implementation through national communication and education activities for consumers, healthcare providers and software vendors.

Commitment to a national approach for digital health

The <u>Intergovernmental Agreement on National Digital Health 2023-2027</u> (IGA) is a commitment by the Commonwealth and all state and territory governments to enable interoperability and connected data across Australia's healthcare settings to support high quality patient care and improve the efficiency and sustainability of the health system.

Under the IGA, all Australian governments have committed to a shared funding arrangement for a suite of key national services to support personalised and integrated health and wellbeing services for all Australians. This commitment, totalling \$129 million across four years, includes a focus on supporting the increased use of My Health Record and working towards national consistency across Australia's healthcare settings (National Cabinet 2023).

Question 1: What is the policy problem we are trying to solve?

The policy problem

The Australian health system is complex with more than 1.1 million individual healthcare providers in public and private services, delivering health services to almost 27 million Australians (Services Australia 2024). Currently, the way a consumer's health information is collected and stored, is fragmented across thousands of clinical information systems



used by healthcare providers. In most cases these systems do not enable the health information to be shared with consumers or with other clinical information systems.

The introduction of the My Health Record system 12 years ago was intended to alleviate this complex problem. My Health Record is designed to give Australians easy access to their key health information. The continued voluntary participation for healthcare providers to upload to My Health Record however means not all key health information is currently shared to a consumer's My Health Record.

As a result, **consumers** are still struggling to access their health information which:

- impacts their ability to participate in their own healthcare and make informed decisions about their health journey, and
- means they experience unnecessary and often costly duplicate tests and follow up appointments which can delay treatment and lead to poorer health outcomes.

Healthcare providers are also frustrated due to a lack of a consistent access to support:

- their clinical decision making, and
- care coordination for their patients.

Pathology and diagnostic imaging reports are one important piece of health information to support healthcare providers' clinical decision making. Currently however, pathology and diagnostic imaging service providers are only sharing around half of pathology reports and one in three diagnostic imaging reports.

Consumers have expressed that they are largely happy to share their health information but are disappointed that My Health Record is not delivering this promise. They want their healthcare providers to upload this health information to My Health Record and use it when they receive healthcare across the health system. Consumers are becoming increasingly frustrated at consistently having to repeat their medical history despite the expansion in digital health (Consumer Health Forum of Australia 2021). In describing the policy problem and content throughout this Policy Impact Analysis we refer to pathology and diagnostic imaging providers specifically, and healthcare providers broadly. Healthcare providers is the term used to encompass a broad range of healthcare providers including primary care providers such as GPs, acute care providers in hospital settings and allied health providers. References to pathology and diagnostic imaging providers are used when describing the issues and possible solutions to supporting the sharing of pathology and diagnostic imaging reports.

The terms consumers and patients are also used broadly to encompass what we know are diverse communities of lived-experience, culture, and geography with varying healthcare needs, experiences and expectations including:

- consumers and patients as the people who engage directly with health services and are the recipients of healthcare
- carers, family members and loved ones who support their care
- people living with disability, chronic and complex conditions including both physical and mental health conditions
- Aboriginal and Torres Strait Islander peoples and their communities
- people from culturally and linguistically diverse backgrounds
- lesbian, gay, bi-sexual, transgender, queer, questioning, intersex and asexual people and their communities
- older people receiving aged care support and those transitioning into aged care, and
- people living in rural, regional and remote communities.

Issue 1 – Consumers expect a more connected experience where their health information follows them across their health and wellbeing journey

In an increasingly digital world, patients expect that their healthcare professionals have much richer and connected access to their medical history, medicines and allergies, diagnostic investigations, and treatment plans. Australia's health system is fragmented, and much of this information is locked away in siloed clinical information systems within healthcare organisations or healthcare settings. This means healthcare providers have limited visibility of their patient's history outside of the information held within their own clinical information systems.

When healthcare providers are unable to access a full, or even a partial, view of their patient's current health information, it puts the onus on the consumer (and their carers) to not only keep a record of their health history, but to also keep their healthcare providers updated on any recent health events, such as hospital admissions. This means that consumers, especially those with complex healthcare needs, need to retell their medical history and personal stories to the different healthcare providers involved in their care.

Consumers want to know that their health information is available to those who have a role in their healthcare planning, treatment and management, and that it follows them as they transition from one care setting to another to ensure they receive the right care, in the right care setting, at the right time.

Availability of key health information is important when consumers move between different healthcare providers and healthcare settings, particularly in emergency situations and for the management of chronic conditions through multidisciplinary models of care. From a clinical perspective, the availability of key health information supports the accuracy and timeliness of communication between healthcare providers and influences quality of care (AIHW 2022).

Australia is not fully utilising the tools we have available now to bring together in one place a summary of a consumer's key health information, as well as a longitudinal view of their health journey. To drive patient-centred healthcare, behavioural change amongst healthcare professionals is required to ensure they share key health information about their patients to My Health Record, subject to patient's instruction not to.

This means key health information <u>must</u> be uploaded to My Health Record by healthcare providers, as a part of routine practice.

The intention of improved information sharing is not for healthcare providers to share their detailed clinical notes, but to communicate key health information needed to support their patient no matter where they present across the health system.

Issue 2 – My Health Record has not yet realised its full potential

The objectives of My Health Record, as set out in the My Health Records Act, are to:

- help overcome health information fragmentation
- improve the availability and quality of health information
- reduce the occurrence of adverse events and the duplication of treatment, and
- improve the coordination and quality of healthcare provided to healthcare recipients by different healthcare providers.

Despite over 90% of Australians having a My Health Record and an increase in the number of healthcare providers registered, there is still around one-in-eleven Australians that do not have an active record (Productivity Commission 2024). Healthcare providers often choose not to share crucial patient information, even when patients explicitly request it (McMillian 2020), contributing to persistent gaps in key health information availability. Consequently, the intended healthcare objectives of the My Health Record system are not being achieved.

'83% of **consumers want to control** their health data, with 71% agreeing that it would improve communications between them and their health professionals' (DHAC 2023a)

The limited sharing of key health information to My Health Record causes disappointment and frustration for consumers and healthcare providers alike (McMillian 2020). Key information gaps lessen the value of My Health Record and the benefits that can be achieved. For instance, the amount of detail contained in an individual record varies, and this inconsistency reduces the inclination of healthcare providers to engage with My Health Record.

Pathology, diagnostic imaging and other diagnostic tests assist healthcare providers to describe, diagnose and/or monitor a consumer's illness or injury. They can also be key to supporting consumers, particularly those with chronic and long-term conditions, to monitor and manage their own health and wellbeing.

In 2020-21, 17.8 million (69%) Australians accessed 204.1 million Medicare-subsidised pathology tests, imaging scans and other diagnostic services (AIHW 2022). However, as of August 2023, pathology and diagnostic imaging providers were only sharing about half of pathology reports and one in five diagnostic imaging reports to My Health Record (DHAC 2023b).

When a clinical decision relies on a pathology or radiology test, the absence of this information in My Health Record represents a critical gap for the treating clinician in the availability of key health information to support coordination of care across healthcare providers and delivery of safe, quality, timely and efficient care for patients. My Health Record has been described as having a 'network effect', with its utility and overall value increasing as more healthcare providers share health information with it (RACGP 2022).

Without a new mechanism to compel healthcare providers to share key health information to My Health Record, its full value will not be realised.

The Strengthening Medicare Taskforce recommended that this action be taken, because poor information flows lead to worse patient outcomes and experiences of care, and increased costs (DHAC 2022).

Issue 3 – Consumers are unable to fully participate and be partners in their own healthcare

Health information is currently fragmented and often difficult for consumers to obtain (Baxby et al. 2022).

The Consumers Health Forum of Australia has noted that consumers are consistently expressing a high level of disappointment at the absence of information in their My Health Record, especially records of diagnostic services and results. Their research on consumer attitudes also identified a significant willingness of consumers to share their health information with their healthcare providers (Consumers Health Forum of Australia 2021).

In addition, approximately 20% of consumer complaints/enquiries/feedback received via the Agency's 'contact us' webpage from January 2019 to March 2024 related to pathology or diagnostic imaging reports not being shared to My Health Record.

Patient-centred care is associated with improved healthcare utilisation and patient outcomes (Larson et al 2019). Shared knowledge and ready access to health information have been identified as core elements of patient-centred care (ACSQHC 2011). Consumers need to be empowered to look after their health and wellbeing and be equipped with the right information to do so (Agency 2023) to successfully deliver patient-centred care.

'When I have informed healthcare, I know what's going on, I know exactly what's happening, before it happens' (DHAC 2023a)

Information gaps in My Health Record can negatively impact consumers' ability to participate and partner in managing their healthcare. When key health information is not shared with My Health Record, consumers do not have access to information that can allow them to:

- better prepare for discussions with their healthcare providers and participate and partner in shared decision making
- exercise choice and more easily change healthcare providers
- more easily monitor and manage their health, with:
 - access to key health information in My Health Record being particularly useful for consumers with chronic and long-term conditions, Aboriginal and Torres Strait Islander peoples and those living in rural and remote areas, and
 - recent examples highlighting that consumer access to key health information in My Health Record can provide a safety net where serious diagnoses have fallen through the cracks (Beavis 2023, Mundy 2023).

Issue 4 – Suboptimal patient outcomes

When health information is not shared with My Health Record, patients experience fragmented care, leading to suboptimal outcomes. Consumer feedback indicates consumers face high levels of inadequate communication with healthcare providers. Of those who saw three or more health professionals for the same condition, one-in-eight reported issues from a lack of communication (Productivity Commission 2023).



CASE STUDY: CONSUMER EXPERIENCE WHEN KEY HEALTH INFORMATION IS NOT AVAILABLE IN MY HEALTH RECORD

Joan is 85 and lives in a residential aged care home. Staff at the facility are concerned that she is becoming agitated. An after-hours doctor is called. Although the doctor has access to the regular medications and medical history documented on Joan's file, the doctor was not able to access the latest pathology results including a blood test and urine test done earlier that day, as she does not have access to the pathology company's results system.

The doctor is therefore not confident in managing Joan at her home, an ambulance is called, and she is transferred to hospital. Subsequently it becomes apparent Joan has a simple Urinary Tract Infection and could safely have been managed in her home had the doctor been able to access the results through Joan's My Health Record.

Access to key health information can lead to better healthcare decision making between clinicians and their patients, reduce the need for unnecessary investigations and hospital admission, improve the accuracy and continuity of treatment, and reduce the incidence of adverse events (Productivity Commission 2023, 2024, ACSQHC 2021).

The Strengthening Medicare Taskforce reported that critical patient health information remains locked in siloed clinical information systems and cannot be easily shared access the health system and care settings (DHAC 2022).

Even where information sharing is possible it is not always happening as often as it should be. These issues must be addressed as poor information flows lead to increased cost and worse patient outcomes (DHAC 2022).

Issue 5 – Cost burden on the health system

Fragmented care imposes a significant cost burden on the health system. Furthermore, a lack of consistently and easily shared key health information between healthcare providers also creates a cost burden on the health system. These cost burdens are especially felt by those with chronic conditions, aged care and disabilities.

Research has found that those healthcare providers who use My Health Record less frequently report that they fail to see the benefits of My Health Record for the patient or for clinical care. These same providers also felt that it should be the patient's responsibility to ask or encourage them to use My Health Record (Mullins 2021). This is in contrast with pharmacists and healthcare providers who exhibit medium and high use of My Health Record, who report more efficient patient care, particularly after hours when a patient's general practitioner or pharmacy may be closed (Mullins 2021).

Placing the burden on consumers or their carers to keep healthcare professionals connected to health events increases the potential for medical errors as important health information, such as diagnoses, or dispensed medicines could be missed or misinterpreted through inaccurate, incomplete, or inconsistent verbal sharing. This can lead to unnecessary or duplicative investigations and avoidable health interventions, as well as associated costs for the Australian Government, healthcare providers and consumers. It can also contribute to misadventure, delayed diagnosis, and inappropriate treatments.

All these factors result in increased costs and inefficiencies, and a missed opportunity to support prevention, patient wellness and sustainability of the system more broadly. The current approach relies on patients relying on the goodwill or good management of private providers to be able to access their own health data. Beyond the savings, near-real time availability of this information can uplift digital health literacy, better inform consumers and support better management and care coordination of chronic conditions.

There is an opportunity to ensure all parties can safely and confidentially share this health information to achieve better health outcomes. Healthcare providers are currently challenged with having incomplete patient information and/or having to log into multiple systems to piece together the information to make informed decisions.

Issue 6 – Limitations to available public health data

Australia's federated system of government means we are unable to easily compare our system to that of similar systems internationally, and it adds complexity to sourcing relevant data.

My Health Record is currently a voluntary system for both consumers and healthcare providers. This means My Health Record data cannot be used, for example, to guide this Policy Impact Analysis. Internationally however, similar systems are mandatory for consumer and/or healthcare providers to use. However, there is variability in how these systems operate, their governing legislation, regulation and the data available regarding their use and/or impacts for consumers, healthcare providers and government/s.

Although data is increasingly becoming available in relation to the use of digital health tools, services and capabilities, there remain limitations in the number and size of studies undertaken. While there is a lack of Australian based data, international research has been predominantly utilised in areas of similar context to Australia's use of digital health.

The Agency as the System Operator of My Health Record is currently able to monitor key consumer and healthcare provider usage statistics and insights, including registrations to participate in the system and viewing of key records such as pathology and diagnostic reports. These statistics are available at <u>www.digitalhealth.gov.au</u>. However, it may not be until further modernisation of the My Health Record activities have been completed that increased and more flexible monitoring of data may become more readily available.

Question 2: Why is government action needed?

Conformant clinical information systems can connect with the My Health Record system and upload key health information including pathology and diagnostic imaging reports.

The majority of pathology and diagnostic imaging providers currently use clinical information systems that have the capability to upload reports to My Health Record. However, some may not have adopted versions that include this functionality or have this functionality turned on. This was made evident during the COVID-19 pandemic when the sharing of pathology results to My Health Record significantly increased (ADHA 2020). Despite this, pathology and diagnostic imaging reports are not shared to My Health Record routinely as a part of clinical practice.

The introduction of a requirement to upload key health information to My Health Record by default seeks to ensure uploading occurs consistently for all providers. A requirement to upload may also provide certainty for consumers and their healthcare providers that My Health Record can be relied upon to be comprehensive and available when needed.

A 2020 Review of the My Health Records Legislation recommended that the Australian Government examine options for tying eligibility criteria for specific government health payments to support increased core clinical content in My Health Record and extensive adoption by healthcare providers (McMillian 2020).

Beyond this, there have been calls to require healthcare providers to share key health information to My Health Record, including:

- a recent Productivity Commission recommendation to use My Health Record as the foundation for sharing and using health data, including by requiring healthcare providers to share relevant health records to My Health Record where a consumer has not opted out (Productivity Commission 2023), and
- a Strengthening Medicare Taskforce recommendation to modernise My Health Record to significantly increase the health information available to consumers and their healthcare providers, including by requiring sharing of health information to My Health Record by default (DHAC 2022).

'Time and time again, a patient goes to their healthcare provider, talks about their conditions, and their tests are not available for the GP to look at and use as part of their diagnosis and treatment decisions. We have got to do better.'

Minister for Health and Aged Care, the Hon Mark Butler MP (Butler 2023a)

Objectives of sharing health information to My Health Record by default

Sharing key health information to My Health Record by default is essential to realise the value of the My Health Record system, so that consumers and their treating healthcare providers have better access to key health information, when and where it is needed. The key objectives of sharing key health information to My Health Record by default are outlined below.

Objective 1: Empower consumers to actively engage as partners in their own healthcare

Consumers, their family or carers, want to be engaged in their own healthcare, or the healthcare of those they care for. The sharing of key health information such as pathology and diagnostic imaging reports is crucial to empower consumers to participate in partnership with their healthcare providers in shared decision making. This approach ensures that consumers independently, and with their healthcare providers, can make informed decisions that meet their clinical needs, expectations of care, and goals and values in their healthcare journey.

When consumers can access and are supported to use and understand their health information, they are better able to actively participate in their care and make informed decisions (DHAC 2022).

Objective 2: Supporting healthcare providers to enhance clinical decision making

Healthcare providers across the health system, from primary to acute settings, rely on key health information, particularly diagnostic information to support their decision making and provide safe and high-quality care. To effectively support partnered decision making, key health information such as pathology and diagnostic imaging reports needs to be available in My Health Record to continue to build trust and confidence in reliable and consistent evidence-based care. Furthermore, this may improve treatment and support better health outcomes, reducing burden on individual consumers, their family and carers, and society.

Objective 3: Making it easier for healthcare providers to coordinate care and participate in multi-disciplinary models of care

Healthcare providers play a crucial role in supporting and coordinating the provision of care, supporting improved treatment and health outcomes for consumers. Effective coordination of care occurs when healthcare providers are supported to communicate key health information and care planning in a collaborative and timely way. This is particularly important for the effective care planning and management of Australia's ageing population, people living with complex chronic health conditions or disability, and for the escalation of support and clinical interventions during an urgent care episode or emergency.

A summary of objectives and intended outcomes of mandating the sharing of health information by default to My Health Record is outlined in **Table 1**. Metrics for measuring progress towards these intended outcomes are further detailed in **Table 18**, **19** and **20** (see Question 7, page 91).

Table 1: Objectives and intended outcomes of sharing health information by default to My Health Record

Share by default objectives	Intended Outcomes	Measurements
1. Empower consumers to actively engage in their healthcare	 consumers can access and utilise their key health information, such as pathology and diagnostic imaging reports, when and where they need it consumers have choice and control to have a My Health Record to decide what information is included and who can access it consumers have choice and control to request their health information not be shared to My Health Record consumers have choice and control of who can access their health information in their My Health Record consumers are empowered to have shared decision-making discussions with healthcare providers and their care team 	 increase in consumer views to My Health Record increase in consumer contact to the Agency's My Health Record help line where accessible consumer sentiment of the My Health Record system, collected periodically to determine impact
2. Support healthcare providers to enhance clinical decision making	 healthcare providers have access to key health information such as pathology and diagnostic imaging reports at the point of care to support clinical decision making healthcare providers are supported to have shared decision-making discussions with consumers 	 increase in healthcare provider views to My Health Record comparative analysis of upload rates of health information such pathology and diagnostic imaging reports increase in healthcare provider views of key health information in My Health Record

3. Making it easier for healthcare providers to coordinate care and participate in multidisciplinary models of care	are to care pate	healthcare providers in a consumer's care team have access to key health information, such as pathology and diagnostic imaging reports, at the point of care increase consumers' care team ability to deliver a connected care experience through shared decision making	 increase in cross viewing by healthcare provider care teams increase views of key healthcare information on My Health Record by healthcare providers
	-	improve the ability of care teams to coordinate and utilise key health information, such as pathology and diagnostic imaging, to escalate and/or provide the most appropriate care to their patient/s	

Limitations

There is limited data currently available to measure the success of the above objectives. The development of further technical capabilities may support this work in the coming years, as it enables more detailed measurement capabilities. For instance, as functionality and technical capabilities improve, more specific time-bound measures can be put in place to track success.

The Agency, as the System Operator, publishes monthly statistics in relation to the My Health Record system via <u>digitalhealth.gov.au</u> that will support the measurement of success of the above listed objectives.

Initiatives attempted to achieve these objectives

My Health Record transitioned to an opt-out model

Following the establishment of the My Health Record system in 2012, consultation with healthcare providers identified that they did not see value in registering to participate as their perception was that there were not enough consumers with a My Health Record. By June 2018, only 5.89 million Australians had a My Health Record (ADHA 2019). In response, a decision was made to transition the My Health Record system to an 'opt-out' model for healthcare recipient registration. This resulted in 90% of Australian's (who decided not to opt out) being registered for a My Health Record in February 2019. As of August 2024, there are over 24 million Australians with a My Health Record, along with 99% of GPs and pharmacies, 97% of public hospitals, 56% of specialists and 39% of aged care providers registered to use My Health Record (ADHA 2024).

Financial incentives provided

Practice Incentive Program eHealth Incentive (ePIP)

Financial incentives, primarily for general practice, have been in place since 1998 to support general operations of clinics. One component of this program, called <u>ePIP</u> (Practice Incentive Program eHealth Incentive) is an incentive payment to encourage general practices to keep up to date with the latest developments in digital health and adopt new technology as it becomes available (Agency n.d.). It aims to help practices improve administration processes and patient care including through the uploading of summary documents to My Health Record.

ePIP is being reviewed to determine its overall effectiveness in supporting and incentivising digital uplift, as part of an <u>overall review (DHAC)</u>. Outcomes to date suggest that while ePIP has resulted in some increase in My Health Record document volumes, it has had unintended consequences of setting minimum expectations and has not resulted in behavioural change.

There is some evidence that ePIP has led to counter behaviours such as delaying upload of summary documents for individual consumers until sufficient volumes of documents are available to maximise incentive payments.

Industry offers to pathology and diagnostic imaging providers

Additionally, the Agency conducted industry offers between 2017 and 2019 to subsidise the development and rollout of My Health Record functionality in the pathology and diagnostic imaging sectors. These industry offers were available to clinical software vendors who serviced these sectors. They were also available to pathology and diagnostic imaging providers themselves, in cases where they had their own in-house systems and software development capability.

Approximately \$1.7 million was disbursed through these industry offers, which resulted in the enhancement of 17 different clinical information systems with My Health Record functionality. This led to a modest increase in connections and uploads to My Health Record in the pathology and diagnostic imaging sectors over subsequent years. However, the fact that there was no imperative for pathology and diagnostic imaging providers to upload to My Health Record meant that many of these enhancements were underutilised. Furthermore, many of the software vendors that initially agreed to participate in these industry offers declined to follow through, as the lack of demand for the functionality from their customers made the enhancement of their software products a non-viable proposition.

Strong relationships and support

The information provided by the pathology and diagnostic imaging industry to healthcare providers and consumers is vital to support the management of acute and chronic health conditions. This sector also conducts tests and scans that allow people to consider preventative health measures such as bowel cancer screening or monitoring cholesterol levels. To ensure a level playing field and equitable contributions to the culture of offering better access to health information, the sharing of pathology and diagnostic imaging reports to My Health Record by default will need to be legislated. Some parts of the sector have flagged that they prefer to understand the detail of the requirements within the legislation to determine the investments that need to be made to be able to comply.

To enhance My Health Record's value into the future, the Sparked program - a collaboration involving the Australian Government, software vendors, provider organisations, peak bodies, practitioners, and experts - will work on advancing national Fast Healthcare Interoperability Resources (FHIR) standards for healthcare information exchange. This may support improving the format of information that is uploaded to My Health Record in the form of structured data and make it easier for consumers and healthcare providers to find specific health information and improve the overall user experience.

Education and engagement

The Agency provides ongoing, routine assistance to support digital uplift of the healthcare sector. This includes providing guidance and support to the software sector to achieve conformance between their products and My Health Record, the provision of sample code and free middleware to reduce the software development burden, and support to healthcare providers in registering for and using My Health Record.

The Agency currently provides a range of information and education support for consumers and healthcare providers, including multilingual resources, webinars, online training courses and materials in written and video format. In addition, the Agency has been undertaking direct engagement and support for public and private pathology and diagnostic imaging providers across every state and territory.

National harmonisation

The Commonwealth and states and territories have been consulting and working collaboratively towards the harmonisation of legislation, regulation and local policies to achieve a nationally consistent approach to health information sharing. This work identified over 100 clinical frameworks across Australia's public health system alone. This variation, coupled with private provider policies and regulations, poses a significant challenge and creates confusion for public and private providers. For more information about this consultation see page 75.

Clinical Reference Group

A <u>Clinical Reference Group</u> has been established by the Agency to provide strategic advice and clinical guidance to the improved sharing of health information to My Health Record to ensure the uploading of pathology and diagnostic imaging results are:

- consumer centred
- focused on delivering high quality information to consumers in line with their preferences, goals and consent, and
- clinically safe, accessible and inclusive.

The Clinical Reference Group is working to provide clarity through the development of nationally consistent guidance for healthcare providers and an enduring clinical governance framework.

Question 3: What policy options are you considering?

This Policy Impact Analysis covers two policy options to address the policy problem:

Option 1 (**preferred**) – create a legislative requirement on prescribed healthcare providers to share key health information to consumers' My Health Records, or

Option 2 – maintain the status quo.

There is no legal requirement under Option 1 or 2 requiring a healthcare provider to check a person's My Health Record for previous results. This will continue to be addressed through a range of communication and education activities as currently provided by the System Operator.

Previous initiatives tried to achieve objectives

As outlined in preceding sections, previous initiatives have attempted to increase the volume of health information available in My Health Record but have not generated critical mass to drive the full value proposition of My Health Record. These activities include:

- changing the My Health Record system from an opt-in to and opt-out model, thereby significantly increasing the number of Australians with a My Health Record
- financial incentives in the form of the ePIP incentive for GP's and industry offers to enhance clinical information systems
- strong stakeholder engagement over the last decade from the Australian Government that includes funding and support of broader digital health initiatives which may enhance health information sharing capabilities
- education and engagement provided by the My Health Record System Operator to support consumers, healthcare providers and software vendors with connection, registration, and use of My Health Record as well as a range of training options, and
- where possible, progress towards national harmonisation of legislation, regulation, local
 policies and procedures with states and territories to reduce confusion for private and
 public healthcare providers of what their obligations are in relation to health information
 sharing. This includes the establishment of a Clinical Reference Group which is providing
 strategic and clinical advice in relation to sharing pathology and diagnostic imaging
 reports.

The ePIP program is intended to encourage general practices to adopt the latest digital health technologies, resulting in increased My Health Record document volumes. However, it has led to unintended behaviours, such as delaying uploads to maximise incentive payments.

The industry offers that subsidised the development of My Health Record functionality in the pathology and diagnostic imaging sectors, led to modest increases in connections and uploads. Despite the efforts of industry and government, many enhancements were underutilised due to the lack of mandatory upload requirements and low demand from customers.

There has been ongoing engagement with the sector, and some parts have indicated they are less likely to share pathology and diagnostic imaging reports by default unless required by legislation. While government recognises the need for ongoing support to enable all providers to connect to My Health Record, a new approach is required to ensure the previous investments by government and industry realise the full benefits.

Ultimately, these previous initiatives have been unable to bring about the scale of behaviour change required to increase the utilisation of My Health Record to improve health information sharing and access across the sector.

Other policy options considered and limitations

Limiting the policy options under consideration reflects the fact that other options have already been attempted over the last decade (see pages 29-31). These other initiatives have not achieved the significant and consistent change in behaviours required of the sector for consistent healthcare information accessibility.

Accreditation schemes

Accreditation schemes are administered by the Australian Commission on Safety and Quality in Healthcare. These schemes provide assurances to the community that healthcare services meet the expected standards for safety and quality. It is a formal program where trained independent reviewers assess evidence of implementation for specified standards.

In considering policy options for improving the sharing of pathology and diagnostic imaging reports to My Health Record, an accreditation-based approach was explored but was not able to be aligned with the timeframes required for achieving the policy objectives. Currently, accreditation schemes for pathology and diagnostic imaging practices assess provider's compliance with accreditation standards every four years. While these schemes ensure adherence to important quality and safety protocols, this timeframe does not align to the proposed implementation of the changes to the legislation.

Work is underway to consult providers on the proposed approach for updating the accreditation standards to assess the new requirement. The new accreditation standards are anticipated in 2026. This timeline diminishes the potential for accreditation to act as an effective lever for changing provider behaviour as the proposed legislation may take effect in 2025.

The current accreditation system involves providers taking formal action if they fail 30% or more of the accreditation standards, and the consequences are limited to the scope of the current status quo requirements. These standards would be updated to align with the proposed legislation and would provide an additional layer of assurance that providers are complying with their obligations post 2026.

Efforts to drive change through accreditation-based reforms in other healthcare areas has mixed success in creating lasting changes in healthcare provider practices. The learnings from other reforms have been applied to the implementation plan. History shows that relying on accreditation alone is unlikely to deliver the necessary improvements in information sharing. However, the proposed changes to the accreditation scheme in 2026 will work in concert with other compliance activities.

Given these limitations, the accreditation option was discarded in favour of two other policy approaches: mandating the sharing of pathology and diagnostic imaging reports to My Health Record by default or maintaining the status quo of voluntary uploads. The former offers a more direct and enforceable path toward achieving the intended policy outcomes, whereas the latter would continue to rely on the existing inconsistent voluntary system.

State and territory governments

All Australian state and territory governments are strongly connected to the digital health agenda with shared investment in national infrastructure such as My Health Record. They have an important role play in supporting national programs and implementation activities including education and change and adoption activities, as well as supporting consistency of messaging and providing valuable feedback on barriers and challenges at a local level.

The exploration of states and territories having a regulatory role in relation to health information being uploaded to My Health Record was not supported. My Health Record is national infrastructure, and the Commonwealth has primary responsibility for its governing legislation and strategic policy.

In addition, with agreement already in place across the sector and with state and territory governments to work towards national consistency to support the flow of health information across our health system, this approach would be a step backwards and as a result was not considered.

It would not be appropriate for the Commonwealth to devolve these responsibilities to states and territories to implement regulation for sharing of health information to My Health Record. In addition, this approach would be unduly resource intensive with each state and territory needing to amend their legislative framework. It would also lead to further discrepancies in approach, adding to the existing large array of competing policies across public and private providers.

Option 1 – Requiring the sharing of health information to My Health Record

How this option will meet the Objectives

Establishing a requirement for healthcare providers to upload reports to My Health Record would support all three objectives:

Objective 1: Empower consumers to actively engage in their healthcare

Option 1 will empower consumers to actively engage as partners in their own healthcare by providing them and their carers with access to their key health information in their My Health Record. My Health Record is a free and easily accessible system for consumers to access their key health information including through the *my health* app. Consumers would be able to come to their appointments with their healthcare provider ready to have a more informed discussion. It may also reduce their need to retell their health history and support their care in the event of an emergency.

Objective 2: Support healthcare providers to enhance clinical decision making

Option 1 would also provide healthcare providers across the health system with access to vital clinical information in near real time which they may otherwise not be aware of or would need to manually identify and request from other healthcare providers.

Objective 3: Making it easier for healthcare providers to coordinate care and participate in multidisciplinary models of care

Ensuring access to key health information from across a consumer's care team would enhance care coordination and improve shared decision making, leading to improved health outcomes.

Overview of new requirements to upload

Under this option, a head of power would be created in both the My Health Records Act and the *Health Insurance Act 1973*. These powers would allow the Minister responsible for the health portfolio to place a requirement on providers to upload (or make available) prescribed types of health information to a consumer's My Health Record. This option would address the head of power and the first tranche of pathology and diagnostic imaging providers that could be in scope. It would also address the scope of services to which a requirement to upload would apply. These would be prescribed through subordinate legislation.

This option would see the introduction of overlapping requirements to maximise uploading, as outlined below.

 Changes to the My Health Records Act to create a requirement on healthcare provider organisations that are also constitutional corporations to upload or make available certain types of health information to the My Health Record system (delegated legislation may define the in-scope healthcare provider organisations and the types of health information required to be shared).

- Changes to the *Health Insurance Act 1973* to require prescribed entities delivering a
 prescribed service covered by Medicare to upload or make available information about
 the service to My Health Record (delegated legislation will detail the services and
 information required to be shared initially this will be information about the test results
 from a pathology or diagnostic imaging service).
- Amendments to the *National Health Act 1953* to enable the Chief Executive of Medicare to use and compare information in My Health Record against Medicare information to determine compliance with an upload requirement.
- Amendments to the *Healthcare Identifiers Act 2010* to authorise the use of healthcare identifiers for purposes related to ensuring compliance with upload by default requirements.

It is intended that enforcement provisions would be implemented with appropriate lead times to enable prescribed entities to achieve compliance. Following enactment of the proposed legislation requiring uploading by default, compliance actions would be available to the Australian Government. This would include powers to match My Health Record and Medicare data from a range of sources to audit healthcare provider compliance. These measures would comply with privacy requirements and would be informed by a Privacy Impact Assessment.

Implications for Medicare payments

It is important to understand that the proposed policy of reclaiming of Medicare payments is limited only to providers and not consumers. Further, any compliance activities will consider any issues or circumstances to be taken into account and would allow the provider to remedy the issue before reclaiming Medicare payments from providers.

Under the My Health Records Act, provider organisations – such as pathology and diagnostic imaging services – register to participate in the My Health Record system to enable the sharing of and access to consumers' health information. The Act extends authorisations to access or share information to a registered organisation's employees, broadly defined in the existing Act.

Under the *Health Insurance Act 1973*, individual providers such as pathologists and radiologists provide the services and attract the applicable Medicare payment.

Medicare usually covers a service at the point it has been provided. Pathology and diagnostic imaging services will often interact with the consumer (blood sample, x-ray) and may conduct the service over a period of time before a final report becomes available. The assignment of a Medicare benefit (where eligible) usually occurs when the consumer has finished undertaking the test/providing the sample, but before the test result is made available.

Medicare payments are proposed to be conditional upon the sharing of prescribed health information to My Health Record. Practically, the condition will only be satisfied once the upload is complete, which may occur after the service has been completed and a claim lodged. Under this option, Services Australia would make payment of Medicare benefit for the prescribed service in advance of upload of the relevant record. This ensures that consumers would not be financially disadvantaged. For example, if a consumer pays for a service upfront, they will receive the Medicare rebate as per current processes. This will not be delayed until upload has occurred. Similarly, should the provider organisation fail to upload, the Medicare benefit would not be recouped from the consumer, but rather would be repayable by the service provider organisation, as a debt to the Commonwealth.

In general, the department can recover the Medicare benefit rebate from a provider even where this rebate has already been paid to the patient. In these cases, the patient still retains their Medicare benefit.

Patients would continue to receive Medicare benefits and would not be disadvantaged.

The proposed legislation would ensure that no consumer is penalised due to a provider failing to meet such a requirement.

Civil penalties may also be applicable for organisations that fail to upload.

It is intended that these changes would only involve minimal administrative effort by healthcare providers and the pathology and diagnostic imaging industry by leveraging existing processes wherever possible. These requirements would be accompanied by compliance powers and penalties for entities captured by the requirement(s). A high-level overview of the proposed legislative changes is shown in **Table 2**.

Primary legislation		Regulations	
My Health Records Act 2012	 Requirement for prescribed constitutional corporations to become registered as My Health Record participants Requirement for prescribed constitutional corporations to upload prescribed records to My Health Record Process to approve extensions to corporations to get registered and/ or prepared to upload records to the My Health Record system Limited exceptions to upload requirements including to protect the safety and wellbeing of consumers Requirements for corporations to record when exceptions apply to prevent their uploading a record Civil penalties for non- compliance with upload mandate and associated requirements 	My Health Records Regulation 2012	 Defines scope of the proposed upload mandate under the <i>My Health Records Act 2012</i> including: types of pathology and diagnostic imaging of constitutional corporations that would be subject to upload requirements types of records that would need to be uploaded timeframes for uploading records additional recordkeeping requirements
Health Insurance Act 1973 National Health Act 1953	 Requirement for prescribed providers to satisfy upload requirement in order to claim Medicare benefits Ability to recoup Medicare benefits as debts to the Commonwealth if prescribed records are not uploaded Enabling information sharing for compliance purposes 	Health Insurance Regulations 2018	 Scope of the upload mandate under the <i>Health Insurance Act</i> 1973: Types of professional services (pathology and diagnostic imaging services initially) for which Medicare payments may be conditional upon upload of information to My Health Record Types of records required to be uploaded in order for Medicare to be payable Timeframes for uploading in order for Medicare to be payable

Table 2: High level overview of the proposed legislative changes

Who will the rule apply to

The proposed approach would see all providers required to upload to My Health Record who:

- provide a prescribed service that is eligible for Medicare, and
- any business that meets the definition of a constitutional corporation and who is of a type prescribed in the regulations.

This approach would not capture:

- public hospitals for non-Medicare funded services
- providers who are charities and not providing Medicare funded services, such as the Royal Flying Doctor Service which does point-of-care testing
- services which have not been undertaken by a pathologist or radiologist (i.e. where the test is undertaken by the using provider e.g. dentist x-rays), and
- Department of Defence or Department of Veterans Affairs (DVA) services, unless provided by a third party which meets the definition of a constitutional corporation.

Requirement to register with My Health Record

Entities who would be captured by the new requirement to upload will need to become a registered healthcare provider organisation (RHPO) or approved repository operator in the My Health Record system in order to comply. A requirement to upload under the My Health Records Act would apply only to an organisation. It would not apply to individual providers unless they also come within the definition of a constitutional corporation.

To become an RHPO, an entity would need to meet the eligibility criteria and apply to the System Operator for registration under the My Health Records Act. The System Operator would still retain the discretion to refuse to register a RHPO, as set out in section 44 of the My Health Records Act.

Further, the System Operator would continue to be able to suspend or cancel registration under section 51 of the My Health Records Act:

- if a provider does not continue to meet its requirements
- if they have contravened the My Health Records Act
- to prevent a contravention or
- to protect the security or integrity of system.

Should the System Operator cancel or suspend registration, then that RHPO and their individual providers would no longer be eligible to provide prescribed Medicare funded services which are conditional on upload.

Requirement to use Healthcare Identifiers

The Healthcare Identifier Service is a national service underpinned by the *Healthcare Identifiers Act 2010* and administered by Services Australia. Using unique 16-digit numbers, providers can attach the correct information to the correct record. This underpins the operation of the My Health Record system.

Organisations need to hold an organisational Healthcare Identifier (HPI-O) to connect to My Health Record. Individual Healthcare Identifiers of healthcare recipients are considered personal information under the *Privacy Act 1988*. Providers are subject to handling requirements and penalties for inappropriate handling of Healthcare Identifiers.

Providers captured by a requirement to upload to My Health Record will need to comply with requirements under the *Healthcare Identifiers Act 2010*.

Extension to meet registration requirement

To support healthcare providers who are not already registered participants in the My Health Record system, it is proposed there would be a process by which an entity could apply for an extension of time from the System Operator.

The System Operator would have discretion to grant or deny an extension request, having regard to the provider's:

- size
- IT readiness
- the organisation's stated plans to become compliant with the requirement to facilitate uploads to My Health Record, and
- any other matter deemed relevant by the System Operator.

A decision made by the System Operator to grant or deny an extension would be an administrative decision subject to review by the Administrative Review Tribunal (Tribunal). Should a provider organisation apply for review, the Tribunal would have the power to make an interim order extending the time in which the entity would have to become registered and comply with a requirement to upload.

Recording where an exception to upload applies

The proposed framework would balance a requirement to upload with the existing exemptions in the My Health Records Act. These include that a consumer can choose not to have a My Health Record and are also able to request their health information not be uploaded to their My Health Record. Requesting healthcare providers may determine that a report should not be uploaded to a consumer's My Health Record due to concern for their health, safety or wellbeing.

The framework would maintain these existing arrangements of the My Health Record system. Where a consumer does not have a My Health Record, information is not shared to the My Health Record system. Access to and communication of health information including pathology and diagnostic imaging reports in these circumstances will be managed between the consumer and their healthcare providers.

Healthcare providers may also be prevented from uploading due to technical issues. For example, not being able to match a consumer's Individual Healthcare Identifier to their My Health Record. Should this occur, healthcare providers would need to record that an exception event occurred.

Who will be impacted and how would the rule affect them

Impact on consumers

All Australians who have a My Health Record will be impacted under this option. Consumers will continue to be able to request a particular document, all documents or certain types of documents not be uploaded to their My Health Record and will maintain the ability to restrict access to their My Health Record or specific documents.

Improved access to health information allows consumers to view their results in advance, minimising expenses and saving time. With prior access, they can adequately prepare for and optimise their follow-up appointments. Consumers' report greater empowerment when they can access their health information and feel more like partners with their healthcare providers and in control of their care (Tsai et al 2020).

CASE STUDY: CONSUMER EXPERIENCE WHEN KEY HEALTH INFORMATION IS AVAILABLE IN MY HEALTH RECORD

David, aged 36, presented to a Medicare Urgent Care Clinic with recurrence of severe headache. Two days earlier, he had been referred by his regular GP for an MRI to investigate recurrent headaches. The Urgent Care Clinic doctor was able to access the recently performed MRI report via My Health Record and reassure David there was nothing life threatening, such as a stroke or brain tumour, and after further clinical assessment could confidently provide appropriate treatment for severe migraine. Had the scan result not been available in My Health Record, David would have been referred to an Emergency Department.

My Health Record has the potential to improve consumer accessibility to their key health information. Shared access to health information can improve communication and relationships between consumers and their healthcare providers (Tsai et al 2020, Baxby et al 2022). It is advised that healthcare providers give guidance ahead of time to best inform consumers before the results become accessible. This enhanced access reduces duplicate testing and imaging, decreases wait times and improves timelines for diagnoses and interventions.

When key health information is available in My Health Record, this can enable consumers to:

- better prepare for discussions with their healthcare providers and participate and partner in shared decision making
- exercise choice and more easily seek care from other healthcare providers, and
- more easily monitor and manage their health, with access to key health information in My Health Record being particularly useful for consumers with chronic and long-term conditions.

Recent examples have highlighted that consumer access to key health information in My Health Record can provide a safety net where serious diagnoses have fallen through the cracks (Beavis 2023, Mundy 2023).

This is supported by international research, which notes that electronic health records have emerged as important digital tools for facilitating engagement and enabling consumers to participate in clinical decision making and communicate with healthcare providers (Steitz et al 2023). More broadly, international research suggests that consumer access to their health information can improve self-management and consumer satisfaction (Giardina et al 2014).

As an example, a study on Canada Health Infoway found as a result of accessing their health information electronically:

- 86% of respondents felt they were more informed about their health
- 80% of respondents felt they could better manage their health
- 71% of respondents reported they were able to set and make progress towards their health goals, and
- 43% of respondents reported they avoided an in-person visit to a doctor and/or emergency room at least once (Canada Health Infoway 2020).

Consumers report that shared access to health information would improve their experience of care by improving communication, not only between them and their healthcare providers but also between healthcare providers in their care team (Baxby et al 2021).



CASE STUDY: CONSUMER EXPERIENCE WHEN KEY HEALTH INFORMATION IS AVAILABLE IN MY HEALTH RECORD

Sumi, aged 60, has long planned a visit to her family in Alice Springs. Just before leaving home, she sees her GP for a blood pressure check-up and blood test. However, in her excitement to travel, Sumi forgets to take her medication with her. She books in to see a GP in Alice Springs for a repeat script.

The GP can use the information in Sumi's My Health Record to find out the medication she needs and can also see the results of the blood test conducted just before she left home which showed no renal or liver problems and that her electrolytes are stable.

Shared access to health information also reduces the need for consumers to retell their medical history to multiple healthcare providers (Productivity Commission 2024). This includes reducing the burden on consumers and their carers to recall complex clinical information in situations of heightened stress including emergency care. Sharing health information improves trust between consumers and their healthcare providers (Tapuria et al 2021) and enables consumers to feel more in control of their care (Tsai et al 2020).

CASE STUDY: CONSUMER EXPERIENCE WHEN KEY HEALTH INFORMATION IS AVAILABLE IN MY HEALTH RECORD

Bill is retired and travelling round Australia in his campervan. He has a prosthetic heart valve and must take warfarin. He is used to clinics using point-of-care-testing for measuring his International Normalised Ratio (INR) which is supplemented by laboratory blood tests.

Bill sets off on his trip knowing that with his satellite internet access he will be able to check his blood test results without needing to wait in each town for the blood to be sent interstate and for the results to come back.

Impact on pathology and diagnostic imaging providers

Pathology and diagnostic imaging providers who are not already registered as a participant in the My Health Record system would be required to comply with the existing <u>registration</u> requirements under the My Health Records Act (Agency n.d.).

While the seven largest pathology providers who complete over 95% of pathology reports already have systems in place to enable uploading to My Health Record, the other 46 private providers responsible for a small percentage of the remaining pathology reports may require changes in systems and processes.

Over 90% of large-scale diagnostic imaging providers have My Health Record conformant software that would allow them to meet a requirement to upload. Remaining providers may require changes in systems and processes.

Record keeping requirements would also apply where the consumer or the provider has determined that a prescribed document should not be uploaded. Providers would need to review their own privacy policies to ensure they are fit for purpose.

In practice, the administration for providers is likely to be low as the number of times an exception is applied is expected to be minimal.

It is not the intent of this option to impact the viability of small providers, particularly in regional or remote areas, from being able to provide Medicare funded services. Ultimately, this option seeks to promote a consistent approach to sharing health information throughout the healthcare sector to improve access for consumers and providers alike, no matter where they are located.

Impact on government

Electronic Medical Record (EMR) systems rolled out across all public hospitals could reduce duplication of pathology tests and imaging, saving around \$355 million annually (Productivity Commission 2024). The implementation of an EMR and alert system would likely reduce overall pathology tests by 6.3% and diagnostic imaging tests by 12.5%, thereby reducing the burden on Medicare (Productivity Commission 2024).

Access to key health information from across health and care settings can help reduce costs and create system efficiencies. This can include improved efficiency in the way patients receive care, and reduced duplication (Productivity Commission 2024).

The Productivity Commission has noted that the potential productivity benefits of greater health information sharing are well established. It is quicker and cheaper to access accurate health information across healthcare providers, leading to better healthcare decisions and reduction in low value care (Productivity Commission 2023).

International research shows that electronic health records have helped reduce costs and create system efficiencies by:

- improving patient flow (Gatiti et al 2021), decreasing healthcare provider workload and speeding up care processes (Tsai et al 2020)
- reducing duplication of tests (Adeniyi et al 2024) and unnecessary tests (Gatiti 2021)
- reducing emergency room visits and avoidable hospital admissions (Tapuria 2021), and
- reducing readmissions (Tsai et al 2020).

More specifically, research has found that use of My Health Record can reduce costs and create system efficiencies by:

- saving healthcare provider time (McBride et al 2018)
- enabling more efficient patient care (Mullins et al 2021)
- reducing duplication of investigations and appointments (Mesquita and Edwards 2020), and
- avoiding unnecessary tests and scans, thereby reducing length of patient stay in the emergency department (Mullins et al 2021).

An additional requirement will be placed on the department and the Agency to manage compliance and data collection activities appropriately and in accordance with all relevant legislation.

The My Health Records Act provides for use of de-identified data and (identified) health information with consent for research and public health purposes. When the relevant technical and governance arrangements are in place, My Health Record data may be available to support researchers and Australian governments in the provision of safe and accessible delivery of health services, in accordance with strict privacy controls for consumers.

There will be increased data-storage expenses for the Australian Government, which may require additional resourcing. The mandate however will not require retrospective uploading of previous results.

Additional Australian Government resourcing will be required to establish an extensions process to be undertaken by the Agency and additional resources to support the department's compliance functions.

Services Australia would see increased costs of issuing healthcare identifiers and other certificates and 'keys' required to connect providers who are not already connected to the My Health Record system. The volume of extension applications and requests for assignment of Healthcare Provider Identifiers is expected to be low in response to the initial in-scope pathology and diagnostic imaging providers.

The Australian Government would also have an obligation to advise consumers and providers, particularly small or sole practitioners, of any new requirement. There may be a need to partner with providers to support information and education efforts for consumers around any change and the importance of booking follow-up appointments where required.

Impact on other healthcare providers

This policy change supports continued good clinical practice and healthcare providers should continue to follow up patients when required.

International research shows that electronic health records have significantly improved patient care and outcomes through more informed clinical decision making, improved coordination of care, reduced medical errors, reduced duplication of tests, and reduced risk of unnecessary procedures and potential harm to patients (Adeniyi et al 2024, Tsai et al 2020).

The Productivity Commission noted that **My Health Record can provide the foundation for a system in which data is shared more comprehensively and used to improve patient and sector-wide outcomes** (Productivity Commission 2023). More specifically, research has found that My Health Record is a vital tool that can improve the quality of clinical decision making and support safer patient care (ACSQHC 2021). This includes research that use of My Health Record can:

- provide efficiencies for healthcare providers in care settings, particularly to support timely decision making (Mullins et al 2022)
- influence clinical decision making (ACSQHC 2021, Mesquita R and Edwards 2020) and be critical to patient care (Mullins et al 2022)
- improve medication management (Mullins et al 2021) and avoid adverse drug events (Mesquita and Edwards 2020, McBride et al 2018)
- improve diagnostic accuracy, particularly where a patient's condition is complex (Mullins et al 2021)
- facilitate transition of care (McBride et al 2018), and
- reduce duplicate investigations and appointments (Mesquita and Edwards 2020).

Impact on software vendors

For over ten years, the Australian Government has been signalling to software vendors that their products should be enhanced to connect to My Health Record. This included subsidising software vendors who service the pathology and diagnostic imaging sectors to enhance their products via My Health Record industry offers conducted in 2017-19. More recently, the Australian Government signalled its intentions through the public consultation conducted in September-October 2023.

For software vendors servicing the pathology and diagnostic imaging sectors, the reform would create an imperative to build My Health Record functionality if it has not been built already. This would provide certainty around the need to invest and would create new market opportunities by expanding the range of healthcare providers that would need the capability to upload to My Health Record.

Any new development requirement to become conformant with My Health Record would divert resources from other pre-existing product development priorities that software vendors will have. The Government resourcing made available through the Australian Digital Health Agency would minimise any impost. These resources include sample code, middleware, and technical advice that are all available to software vendors free of charge.

It is important that all pathology and diagnostic imaging providers are enabled to support this change. To allow the industry to transition, penalties (including the reclaiming of Medicare payments from pathology and diagnostic providers, not consumers) will not apply until six months after the new laws have come into effect. In addition, providers who require more time to complete the technical work to connect to the My Health Record system can apply for an extension.

Option 2 – Maintain the status quo

Under this option, it would remain voluntary for healthcare providers to upload health information, including pathology and diagnostic imaging reports, to a consumer's My Health Record. Providers would continue to have the option to register as a participant to the My Health Record system at any time, however there would be no requirement for them to use or add health information to a consumer's My Health Record.

How this option will meet the Objectives

Option 2 would have significant limitations in being able to meet the objectives to support the sharing of key health information.

Consumers may continue to only have partial access to their health information stored in My Health Record, which would be reliant on continuing voluntary uploading by all healthcare providers, including pathology and diagnostic imaging providers. There are providers across the sector who have already indicated they will not voluntarily move to share pathology and diagnostic imaging reports by default and would only do so if a legislative requirement were put in place.

This would leave consumers with no option but to maintain a record of their health history by other means such as continuing to use paper-based copies. It could mean consumers may continue to experience unnecessary duplicate testing which can lead to unnecessary radiation exposure and costs associated with follow-up appointments (RACGP 2013, AMA 2024).

Option 2 would limit key health information available to healthcare providers across the health system at the point of care. Providers would not have reliable access to vital clinical information in near real time to support their clinical decision making which may lead to ordering unnecessary duplicate tests or needing to manually track down and request this information from other healthcare providers. Care coordination would be impacted with no easy ability for consumers and all their healthcare providers to have the necessary access to their diagnostics information when they need it.

This option would be limited to healthcare providers, including pathology and diagnostic imaging providers, voluntarily uploading key health information to My Health Record which has not been successful in broad range behaviour change to date. It would also rely on software vendors uplifting their products to support a more seamless user experience.

Impact on consumers

Consumer health information would remain siloed in clinical information systems and not easily accessible to the consumer or their care team, requiring a need for consumers to retell their medical history.

Consumers seeking to monitor results for chronic conditions may need to manually collect information. Consumers *may* also be subjected to unnecessary radiation exposure should unnecessary/duplicate diagnostic imaging tests be ordered. The costs associated with these unnecessary/duplicate tests would be borne by taxpayers through Medicare rebates and patients through any out-of-pocket expenses.

Consumers may also not receive or seek timely follow up healthcare if reports are not reviewed or actioned by the requesting healthcare provider in a timely manner. Should repeat testing need to occur, it may be cumbersome for consumers to find a provider with availability, especially if the test required is complex and providers only offer limited services for that type of testing.

Impact on pathology and diagnostic imaging providers

All pathology and diagnostic imaging providers would not be required to register as participants in the My Health Record system. Many providers are registered but there are benefits to having as many as possible registered and fully participating in the My Health Record system.

Diagnostic imaging providers who require previous tests to assist with baselining their diagnoses and results would need to rely on consumers remembering the location and date of their previous results in order to access this information, thereby consuming additional resources. There may be a perception that some pathology and diagnostic imaging providers could receive more income from unnecessary tests being requested. While many providers strive to support patients with efficient services, there is some evidence that there are opportunities to reduce duplicate testing resulting from a lack of access to some reports.

Impact on other healthcare providers

General practitioners, specialists and hospitals would have to continue to rely on health information in their own clinical information systems and may not have access to all relevant information to support clinical decision making or care coordination. This in turn may lead to duplicate tests being ordered. The costs of these duplicate tests would be incurred through Medicare rebates and patients through any out-of-pocket costs. In addition, there are costs for consumers and providers in the additional time to complete these duplicate tests. This would be of particular concern within a hospital or emergency care settings where there are limited facilities for pathology and diagnostic imaging testing.

Ensuring the flow of health information in a more reliable and consistent way provides the opportunity to reduce the accumulative impact of lost time for all healthcare providers needing to locate previous diagnostics reports. This is particularly the case for the management of chronic conditions, such as diabetes, where the use of My Health Record enables consumers to get the support they need wherever they go (Diabetes Australia 2023).

Impact on software vendors

There is negligible impact on the software industry. There would be less impetus to make their products conformant with My Health Record which would continue the cycle of siloed health information.

Impact on government

The rate of duplicate or unnecessary testing is likely to continue. With many tests receiving a Medicare rebate, the Australian Government (and taxpayer) would continue to pay for duplicate or unnecessary tests.

Question 4. What is the likely net benefit of each option?

This section outlines the benefits and costs for each of the two policy options proposed in this Policy Impact Analysis. The approach to determine the benefits and costs of each option included desktop research, stakeholder consultations, and economic modelling based on available information and data.

There are several key assumptions that have been made to base numerical calculations as the basis of the regulatory burden assessment costs and benefits for each policy option. Detailed information on the data and assumptions used to inform the benefits and costs assessments can be found in Appendix B.

Further, the Office of the Chief Health Economist (OCHE), within the department, was asked to review the calculation of net benefits in the Policy Impact Analysis. These were assessed to have been accurately calculated.

Selection of the preferred option

The selection of the preferred option is guided by the extent to which the option meets the policy objectives, the regulatory burden and associated costs to the sector and the Australian Government, and the benefits of implementing each option. The preferred option will be chosen based on the balance of these factors, delivering the highest net benefit overall.

With the preferred option, there is potential for a reduction in duplicate testing due to improving access for providers and consumers to pathology and diagnostic imaging reports in My Health Record. This may also result in a reduction in waiting times to book an appointment for a test.

Best endeavours have been made to provide accurate estimates, noting that due to the voluntary nature of uploads to date there can be a lack of quantifiable data for a cost-benefit analysis. It is possible that social, environmental and health impacts that have been harder to quantify are skewed or undervalued. To address this limitation, a shorter time horizon was used to prevent the effect of an exponential growth in costs impacting the calculated net benefit, or potentially undervaluing future benefits.

Where possible, monetary values were calculated on estimated and anticipated benefits. For example, in the case of the consumers perspective, the benefit of no longer needing to attend unnecessary follow-up appointments was calculated. There are other health benefits associated with the consumer of more timely access to healthcare where needed in emergency situations. Calculating the monetary value of these health benefits was not feasible but these benefits should not go unnoticed.

In the case of pathology and diagnostic imaging providers, the estimated benefits include cost savings due to reduced time spent on clinical inefficiencies, establishing test history, results and communication. Other anticipated benefits that are difficult to calculate monetary values for include reputational benefits and a reduced administrative burden that may impact clinicians day-to-day.

Options were evaluated based on net benefit overall, with the net benefit being the difference between the total benefits and total costs of the policy in monetary terms. The rationale for using highest net benefit is that it provides the greatest economic value and maximises societal welfare by selecting an option where benefits most substantially outweigh costs.

This cost benefit analysis considers the perspectives of consumers, healthcare providers, pathology and diagnostic imaging providers, and the Australian Government. Impacts for these stakeholder groups under Option 1 (mandate the sharing of reports to My Health Record) are compared to the impacts of Option 2 (status quo).

Regulatory burden cost estimate timeframes

The regulatory burden framework requires the consideration of costs over a 10-year projection as averaged out across each year. However, for the purpose of this Policy Impact Analysis, and considering the available data, this projection is considered not to be feasible as it would provide an inaccurate view into years of implementation and would inaccurately influence decision making.

Consequently, a timeframe range of the first year of implementation up to year four post implementation was used. This is due to concurrent digital health programs of work maturing that may directly or indirectly affect the My Health Record system and the broader health system capabilities. The range of work in progress to uplift and modernise My Health Record is expected to create additional benefits that cannot yet be estimated. Indications are that in the coming years other costs may be further alleviated, and benefits may also increase.

Data limitations for costs and benefits

Within this Policy Impact Analysis, it should be recognised that while the available data provides a solid basis for analysis, there are limitations that impact the clarity of some cost and benefit estimates. These limitations stem from gaps in detailed usage data, provider behaviour, and the unknown precise costs of compliance and technology implementation for government and providers to implement the mandate.

These constraints have a limited effect on the precision of the analysis, but the available data has informed reasonable estimates. The data limitations do not detract from the broader projections of the policy's potential, overall direction, and anticipated benefits.

If the proposed legislation is implemented, stronger benchmarks and a larger data set will be available to provide more precise estimates. This will inform any future expansion of the mandate to other parts of the health sector to build on the benefits and cost savings it will deliver.

For further detail on assumptions and estimates considered in this Policy Impact Analysis, refer to Appendix B.

Net benefit Option 1 – Require sharing of health information to My Health Record by default

Overview

The proposed requirement to share key health information to My Health Record by default will have significant positive effects for Australia's health system by increasing the availability and accessibility of health information.

To outline the impact, within the 2020-21 financial year 17.8 million (69%) Australians accessed 204.1 million Medicare-subsidised pathology tests, imaging scans or other diagnostic services.

The benefits realised to date since the 2023-24 Budget announcement in May 2023 of the intent to make it a rule to share health information to My Health Record include (see **Table 3** below):

- increase in My Health Record pathology and diagnostic imaging provider registrations
- large scale providers progressively moving to sharing by default currently.

Who is affected and what are the economic, social and environmental costs and benefits?

Overview

An optimised benefits model has been used to estimate a high and low range use of pathology and diagnostic imaging services. The overall estimate is based on more modest assumptions.

Mandate claim

This model assumes a steady state, where the mandate is already implemented compared to if it was not implemented. Where available data is limited, assumptions have been made to inform outputs of the model used to determine benefits and costs, including:

- based on literature review (Chami et al. 2021), duplication in pathology and diagnostic imaging testing is estimated to be 5% of MBS services
- it is estimated that up to 80% of diagnostic imaging and pathology reports would meet criteria requiring uploading to a consumer My Health Record
- the Agency forecasts that most of the pathology sector could transition to uploading by default within one year, using current upload rates as a baseline
- the Agency forecasts that most of the diagnostic imaging sector could transition to uploading by default within two years, using current upload rates as a baseline

- it is estimated that viewing rates by healthcare providers could grow by 30% from current baseline rates for both diagnostic imaging and pathology, and
- the model includes an estimate that 50% of the time a healthcare provider views a relevant diagnostic report in a patient's My Health Record they will make a decision not to request a diagnostic test.

Further details and other assumptions can be found in Appendix B.

The impact of these identified assumptions means the full extent of the costs and benefits of the mandate cannot be claimed. While the mandate will significantly contribute to overall outcomes, these factors will also impact. Therefore, a conservate estimate of 5% has been applied across all potential benefits and costs. This will be highlighted in calculations as a '5% mandate adjustment'.

Pathology and diagnostic imaging providers

Most pathology and diagnostic imaging providers have access to conformant software to enable them to upload pathology and diagnostic imaging reports to My Health Record. Some providers will need time to procure or upgrade systems to enable them to comply with the proposed mandate.

The Australian Government will consider the needs of those providers who would require additional time to procure or upgrade to My Health Record conformant systems. Looking to the future, alternative technological solutions may become available to assist in bridging the gap for the burden on providers. Low-cost options could include utilising current Secure Messaging capabilities for a small fee per upload, which could occur at the same time a report is sent through Secure Messaging to the requesting healthcare provider, effectively sending a copy to My Health Record at the same time.

Table 3 provides an analysis of the current private provider upload capability and likely impact on these service providers.

	Pathology (approx. 53 in-scope private providers)	Diagnostic imaging (approx. 300 in-scope private providers)
Large providers	 > 1 million MBS claims per annum seven meet this criterion and account for approximately 98% of private MBS pathology claims it is expected all could achieve the requirement to upload as they already have access to My Health Record conformant software 	 > 10,000 MBS claims per annum approximately 130 providers meet this criterion and account for approximately 98% of private MBS DI claims of those, approximately 90% are using My Health Record conformant software the majority of these with conformant software are not currently uploading
Small providers	 four of 46 are currently uploading to My Health Record. few (if any) of the other 42 have a viable technical path to connect to My Health Record in the near term) 	 approximately 170 providers most have My Health Record conformant software (but less is known about these providers' practice in uploading to My Health Record)

Table 3: Summary of the private provider market

Pathology and diagnostic imaging providers may benefit from improved access to previous reports and tests, enabling comparison of current and historical medical information. Reducing time spent on manual data tasks leads to improved efficiency, improved resourcing for pathology and diagnostic imaging providers, and fewer report errors.

Healthcare providers, pathology and diagnostic imaging providers and software vendors across the health system have already invested in system upgrades to allow for sharing of key health information. These investments would not need to be duplicated and would support their ability to start sharing by default. The remaining pathology and diagnostic imaging providers which are not using conformant My Health Record software will need to invest in solutions according to their business needs. Uplifting this capability may create equity of investment across the sector to improve provider readiness for integrating future digital models of care, enhancing the interoperability of the health system.

Impact on smaller pathology and diagnostic imaging providers

Smaller pathology and diagnostic imaging providers currently without access to My Health Record conformant software may face greater burdens compared to larger providers due to the need to procure or upgrade their systems. For small providers with fewer resources, the costs associated with system upgrades could represent financial and operational strain without lower cost alternatives coming to market. As larger providers already have systems in place, this imbalance could lead to a disparity in how quickly smaller organisations can comply with the mandate.

Tailored support for these groups, such as extended timelines and support and guidance to connect with the right product, could be considered. This approach would ensure that both large and small providers benefit equally from the efficiencies of a connected digital health ecosystem.

Health systems and administrators

Sharing health information reduces administrative burdens and can streamline workflows. It also supports greater transparency, best practice and interoperability.

Having access to more comprehensive health information may reduce administrative costs and improve resource allocation through the reduction of unnecessary pathology and diagnostic imaging tests. It is possible waiting times will reduce, and this will allow providers to offer earlier appointments to consumers. For some conditions, early diagnosis leads to better health outcomes that reduce cost and suffering as less invasive treatments are required.

Careful use of de-identified aggregated health data improves overall health system planning. This can also inform data quality improvement opportunities.

The efficiency and cost-saving benefits of a connected digital health system are expected to be even more impactful for smaller and rural healthcare providers, where resources are often stretched. Ensuring that these groups receive adequate support to implement the changes would result in more equitable access to system-wide improvements. Larger healthcare providers will likely experience a smoother transition, highlighting the importance of tailored interventions for smaller systems.

Summary: Measure of benefits and cost to pathology and diagnostic imaging providers

The proposed mandate is expected to have nil or negligible cost implications for large pathology and diagnostic imaging providers. Large pathology providers account for 98% of MBS pathology claims and all have access to and are able to upload to My Health Record. Most large diagnostic imaging providers (90%) use My Health Record conformant software and are able to upload reports. Some costs may be incurred to develop and operationalise minor changes to administrative processes to comply with the mandate.

There are 46 small pathology providers, and four are currently able to access My Health Record conformant software that enables reports to be uploaded to My Health Record. This indicates it is possible for smaller providers to comply with the mandate. The remaining providers have identified barriers such as lack of technical capability to purchase, implement and train staff on My Health Record conformant software to be able to access the system and upload records. Although a cost impost will be incurred by these providers to implement conformant software, an extensions process will allow these providers to apply for more time to obtain appropriate technical capabilities to adhere to the mandate.

Smaller diagnostic imaging providers will also have access to My Health Record conformant software and the ability to apply for an extension of time to comply with the mandate, if required. There will also be costs occurring to update processes and train staff to adhere to the mandate.

The mandate may impose additional administrative costs on some pathology and diagnostic imaging providers. There may also be some time impost, such as searching and data matching consumer Healthcare Identifiers. The process of uploading reports may have less impact as these are already being sent to requestors and the software is capable of sending reports to the My Health Record system within the same transaction. Future digital health initiatives are being considered to address useability and ease of connection to the system.

Several assumptions have been made to determine the claim of benefit and cost savings, see Appendix B for a list of assumptions. Benefit and cost claims are outlined in **Table 4.**

Table 4: Pathology and diagnostic imaging provider costs and benefits of implementing the mandate

Pathology and diagnostic imaging provider			
Benefit	To be determined in consultation with industry and further development of an evaluation framework over the next 12 months.		
Cost	Pathology \$2,087,750	Diagnostic imaging \$8,852,900	
	Total pathology and diagnostic imaging costs: \$10,940,650 (Year 1) Costs for ongoing years will be determined following evaluation and monitoring of mandate outcomes.		

The anticipated benefits to pathology and diagnostic imaging providers may include but are not limited to:

- a reduction of customer enquiries and calls associated with locating test reports to allow for better use of resources
- time savings for pathology and diagnostic imaging providers when transferring test reports and results to consumers and other healthcare providers, and
- increased pathology and diagnostic imaging provider customer satisfaction due to information being accessible in My Health Record.

Consumers

Streamlining access to health information, reducing administrative burdens, and saving time and money on unnecessary appointments are all added conveniences for the consumer.

Consumers having access to their health information allows them more self-agency and confidence in their own care. This enables them to make more informed decisions, be better prepared when attending healthcare appointments, and participate more actively as partners in their care to the extent they choose.

Timely and predictable access to test results can reduce anxiety, uncertainty, and unnecessary or duplicate testing. This results in saving time and money for the consumer and is crucial for more vulnerable people in our community, such as those with chronic illnesses and disabilities. This cohort within the population often require frequent testing and consultations. For those in rural and remote areas, including Aboriginal and Torres Strait Islander peoples, access to timely test results can reduce the need for repeat visits to healthcare facilities. These locations may be difficult to reach and the requirement to upload reports offers significant time and cost savings.

Comprehensive health information enables more accurate diagnoses and the development and maintenance of treatment plans for consumers. This supports a reduction in health inequality and improves the safety and quality of more coordinated care that they access.

Enabling all healthcare providers involved in a consumer's care to safely store and access consumer health information reduces the risk of errors. It also may lead to less duplicate testings and enhancing continuity of care. The potential benefits are even larger for consumers living with a complex chronic illness or disability that requires them to interact with the health system frequently.

Supporting safe consumer access to sensitive results

Standards are currently in place to support healthcare providers including pathology and diagnostic imaging providers to manage adverse outcomes from unexpected test results. This includes the ability to not share a report to a consumer's My Health Record without follow-up consultation from a healthcare provider. At the time of care, it is expected that healthcare providers may engage in shared decision making in collaboration with patients to support their individual needs and circumstances.

Existing arrangements regarding adverse events would inform legislative exceptions, clarifying when it may be inappropriate to share specific information. This approach prioritises patient wellbeing, ensuring that sensitive information is communicated compassionately and effectively.

As outlined on page 31, the department in conjunction with the Agency have established a <u>Clinical Reference Group</u> to ensure appropriate clinical guidance in decision making for healthcare providers.

Impact to vulnerable populations

For consumers often heavily reliant on the health system—such as Aboriginal and Torres Strait Islander people, those with complex conditions or disabilities, and those in rural or remote areas—access to health information is crucial. These consumers often face barriers such as geographic isolation, socio-economic disadvantage and systemic inequities. Ensuring easy access to health information may help reduce these disparities by supporting consistent and continued care that is well coordinated across multiple providers.

For Aboriginal and Torres Strait Islander peoples, this can significantly reduce the fragmented care they often experience, allowing healthcare providers to make better-informed decisions that are sensitive to their cultural and potential geographical contexts and impacts.

For marginalised groups, such as people experiencing stigma or inequity in healthcare, the ability to access and share comprehensive medical information across different healthcare settings can reduce the chance of misdiagnosis, inappropriate treatment, or overlooked health issues.

In remote and rural areas, where healthcare services are more limited, this continuity of care is vital, ensuring that care is more consistent even when consumers need to travel or consult with multiple healthcare providers.

Summary: Measure of benefits and cost to consumers

Consumer costs are expected to be nil as the proposed mandate will have no additional impost. It is likely consumers will experience significant benefits and cost savings due to these changes.

Provider cost impacts will vary and over time returns will accrue in any investment to comply with the changes. This will occur through productivity increases and operational efficiencies that allow waiting times and administrative efforts to reduce.

The way the changes are intended to be implemented seeks to provide time and support for providers and the pathology and diagnostic imaging industry to transition. It is hoped that these changes may also enable providers and the industry to realise benefits that lead to greater efficiencies.

Implementation of the mandate will claim a benefit to consumer costs by a reduction in attending unnecessary follow-up appointments. Cost saving benefits have been presented at both high and low optimised benefits and separated between pathology and diagnostic imaging savings. Consumers may no longer need to request copies of their results or attend follow-up appointments solely to view their results. This minimises both expenses and time spent. With prior access to their results, consumers can adequately prepare for and optimise their follow-up appointments. It is recommended that healthcare providers offer guidance ahead of time to best inform consumers before their results become accessible.

Improved access to health information also reduces duplicate testing and imaging, which can decrease wait times and improve timelines for diagnoses and interventions. This is particularly beneficial in emergency settings where quicker access to information can hasten care timelines, especially for individuals with additional needs.

Furthermore, having access to previous diagnostic information allows healthcare providers to make more timely care decisions without the need for duplicated testing. This saves consumers and their carers time and resources associated with attending unnecessary follow-ups. With the promotion of consistent treatment strategies, unnecessary discomfort and costs to the consumer are reduced.

Cost-saving benefits have been presented at both high and low optimised levels and are separated between pathology and diagnostic imaging savings. By making earlier decisions based on accessible information, doctors can further reduce consumer costs.

This mandate primarily focuses on the interaction between general practitioners (GPs) and patients, ensuring that the benefits are directly felt in the most common healthcare setting. Proposed benefits in the high range have been calculated with an assumed 50% rate of unnecessary follow-up appointments, and 25% in the low range.

The calculation of the benefit to consumers where costs are saved from not attending unnecessary follow ups considers the value of consumer time (as average hourly earnings by testing participation rate), average travel time to appointments, average waiting room time, length of consultation, and number of GP attendances (from 2022 to 2023).

Several assumptions have been made to determine the claim of benefit and cost savings, see Appendix B for list of assumptions.

A conservative estimate of 5% has been applied to the calculated high and low costs in recognition that sharing by default is only one contributing factor to achieve the full benefit. This has been applied in recognition that there are many other factors that affect reasons for follow-up appointments with GPs by consumers post testing, as there are some circumstances where a follow-up is necessary or is unavoidable.

Benefit and cost claims are outlined in Table 5.

Consumer			
Benefit	Consumer savings of not attending unnecessary follow up appointments with mandate		
	Pathology Diagnostic imaging		
	High: \$43,518,560	High: \$9,973,003	
	Low: \$21,759,280 Low: \$4,986,501		
	Combined total		
	High: \$53,491,563		
	Low: \$26,745,781		
Cost	Nil		

Table 5: Consumer costs and benefits of implementing the mandate

Healthcare providers

Healthcare providers may face initial costs and resource allocation challenges related to training and implementation of new data-sharing protocols.

Healthcare providers will have access to high quality, timely and complete health record histories for each consumer, allowing them to compare results over time and support enhanced clinical decision making at the point of care.

Reducing the time spent gathering information from different sources allows more time for consumer care. Healthcare providers can securely and conveniently review crucial consumer health information.

Efficient communication and up-to-date data sharing between healthcare providers enables enhanced collaboration, contributing to more tailored healthcare management and better health outcomes.

Impact to smaller and geographically isolated healthcare providers

Healthcare providers are likely to experience varying levels of initial costs and resource allocation challenges, particularly regarding training and implementation of new data-sharing protocols. Smaller healthcare practices, rural providers, and those with limited financial resources may face these challenges more acutely than larger or urban-based providers.

In accessing high-quality, timely, and complete health record histories, providers in wellresourced, urban settings may benefit more quickly due to existing infrastructure and greater staffing levels, while rural or under-resourced healthcare providers might experience delays without additional support. Ensuring equitable access to training, technological support, and compliance timelines will be essential to prevent disparities in care quality.

Furthermore, while larger healthcare institutions may have robust systems for communication and data sharing, smaller clinics or rural providers could require more time and resources to achieve similar efficiency. To promote balanced improvements in healthcare outcomes, it is vital to provide equitable access to digital infrastructure and ongoing technical support across all provider types.

Care coordination

Mandated data sharing can significantly improve communication among healthcare providers, facilitating better coordinated and integrated care plans for consumers.

Real-time access to updated consumer records can enhance the responsiveness of healthcare services, particularly in emergency situations, reducing avoidable adverse events and hospital admissions.

Sharing health information can streamline the process of care transitions, reducing delays and potential errors during patient handovers.

Benefits for acute care settings

The mandate to share pathology and diagnostic imaging reports with My Health Record by default offers significant benefits for acute care settings, particularly in enhancing the quality and efficiency of patient care in hospitals.

Access to essential medical information is critical when patients present to emergency departments where timely decision making can be lifesaving. Previous studies have identified that the top three pieces of medical information needed in such acute scenarios include current medications, allergies, and previous diagnostic results.

My Health Record can facilitate access to these crucial pieces of information, enabling healthcare professionals to make informed decisions quickly and effectively. However, there is currently a lack of data that quantifies the impact of accessing pathology and diagnostic imaging reports through My Health Record in acute care settings, including hospitals, making it difficult to illustrate the full extent of its benefits.

While quantifying data utilisation in acute care settings remains a challenge, it is reasonable to conclude that access to comprehensive, real-time medical information through My Health Record could streamline workflows, reduce redundancy in testing, and ultimately improve patient outcomes. Addressing this gap in data will be essential for future work to demonstrate how My Health Record meets the needs of acute care providers, including those in hospital settings, and enhances the delivery of care in critical situations.

Summary: Measure for benefits and cost to healthcare providers

Healthcare provider costs due to the implementation of the mandate is nil or negligible. Healthcare providers have existing legislative requirements to retain records, meaning no additional costs would be required to amend workflows or processes. Although healthcare providers can upload to My Health Record, this mandate does not require them to do so.

Mandating the requirement to upload pathology and diagnostic imaging reports to My Health Record can claim a benefit to healthcare providers by reducing time spent on unnecessary clinical and administrative activities, establishing consumer test history, results and communication. Cost savings benefits have been presented at both high optimised benefits and low conservative benefits and separated between pathology and diagnostic imaging. High proposed benefits have been calculated with an assumed five-minute efficiency improvement per test with the low at two minutes.

A conservative estimate of 5% has been applied to the calculated high and low costs in recognition that sharing by default is only one contributing factor to achieve the full benefit.

Several assumptions have been made to determine the claim of benefit savings, see **Appendix B** for list of assumptions. Benefit and cost claims are outlined in **Table 6**.

Table 6: Healthcare provider costs and benefits of implementing the mandate

Healthcare provider			
Benefit	Cost savings due to reduction in time spent on clinical inefficiency, establishing test history, results and communication.		
	Pathology Diagnostic imaging		
	High: \$16,610,417	High: \$4,331,250	
	Low: \$6,644,166 Low: \$1,732,500		
	Combined Total		
	High: \$20,941,667		
	Low: \$8,376,666		
Cost	Nil/negligible		

Government

Tracking of health trends, outbreaks and the effectiveness of interventions improves informed public health decision making and ultimately health outcomes.

Access to comprehensive health data supports evidence-based policy decisions including enhanced system planning, timely and accurate policy decision making and evidence based public health interventions.

Better data helps in efficient allocation of healthcare resources and planning to target, manage resources, deliver cost efficiencies for the health system and improve care coordination and consumer outcomes.

Facilitating preventative health measures, improving care coordination and health outcomes represents significant economic impacts through optimising healthcare spending, reducing burden on the public system and increasing wellbeing and productivity.

Summary: Measure for benefits and cost to government

Cost to the Australian Government will occur through both compliance activities and the implementation and management of an extensions process. To ensure pathology and diagnostic imaging providers comply with the mandate requirements, it is expected that costs to the department and to the Agency will be required to maintain regulatory functions for compliance. To support smaller providers to comply with the mandate, resources will be required for the Agency to establish a time-limited extensions process.

Benefit to the Australian Government resulting from the mandate may see a reduction in MBS costs due to a reduction in duplicate testing. As the uploads of pathology and diagnostic imaging reports increase, the proportion of healthcare providers viewing these reports may increase. Previous research suggests that increased viewing of reports leads to changes in healthcare provider requesting behaviours, leading to a reduction in duplicate testing. Estimates of costs span a four-year period, commencing from the 2023-24 financial year.

It is estimated that full realisation of these benefits may not be seen for 1-2 years, which supports the conservative benefit costings listed below. The Australian Government typically applies a 7% discount rate when evaluating projects. However, 7% have been scrutinised for undervaluing future benefits. The UK and New Zealand often use lower discount rates (ranging from 3.5%-5%) to avoid undervaluing future benefits and account for lower opportunity costs in these contexts. Although best practice, a discount rate was not applied in this context as a conservative estimate of 5% was applied. In addition, due to the shorter timeframe the effects of applying a discount rate were considered negligible.

The Agency has secured funding to support the success of the mandate through the development of a comprehensive communication and education plan. Further communication and education strategies and costs will be determined over the coming 12 months and would be subject to decisions by the Australian Government.

A conservative estimate of 5% has been applied to the calculated benefits in recognition that sharing by default is only one contributing factor to achieve the full benefit.

Several assumptions have been made to determine the claim of benefit savings, see Appendix B for a list of assumptions. Benefit and cost claims are outlined in **Table 7.**

Government			
Benefit	Reduction in MBS costs for duplicate tests		
	Pathology	Diagnostic imaging	
	\$2,663,643 (5%)	\$2,941,190 (5%)	
Cost	Implementation: Compliance, extensions and communication and education activities		
	\$5m		
	(Two-year total spend)		
	$\underline{\text{Note:}}$ these are estimates and would be subject to future decisions of the Australian Government		

Table 7: Government costs and benefits of implementing the mandate

Moreover, while costs to the Australian Government have been outlined for compliance activities to support the implementation of Option 1, this figure does not account for associated IT and technology related costs to support data transfer and reporting. At the time of the Policy Impact Analysis, specific details regarding the scope of compliance activities including the required data to perform this function has not been finalised. The Australian Government will work to further define the requirements for compliance activities, and more information will be made available to articulate additional costs to support the implementation of Option 1.

Analysis of the net benefit of Option 1 – Requiring the sharing of health information to My Health Record

Net benefit

The net benefit of requiring the sharing of health information to My Health Record is likely to be significant. While there are upfront costs and challenges associated with implementation, the long-term benefits in terms of improved health outcomes, cost savings, and enhanced care coordination are substantial. The social benefits, particularly regarding patient safety and empowerment, further underscore the positive impact of this policy. Addressing privacy concerns and ensuring robust data management practices will be crucial to maximising these benefits. A summary of costs and benefits for Option 1 - Requiring the sharing of information to My Health Record is outlined in **Table 8**.

Summary

Table 8: Summary of benefits and costs of Option 1 – Requiring the sharing of information to My Health Record

	Pathology and diagnostic imaging providers	Consumers (annual)	Healthcare providers (annual)	Government
Benefit		High: \$53,498,092 Low: \$26,749,046 Streamlined access to health information reduces administrative burdens, saves time and money, and enhances consumer confidence and care coordination.	High: \$20,941,667 Low: \$8,376,666 Access to comprehensive and timely health records enhances clinical decision making, care coordination, and overall health outcomes. Enhancement in responsiveness during emergencies and streamlines care transitions, reducing delays and errors.	\$5,604,833 (over four years) Access to comprehensive health data enhances public health decision making, resource allocation and care coordination, leading to better health outcomes, cost efficiencies and significant economic impacts.

	Pathology and diagnostic imaging providers	Consumers (annual)	Healthcare providers (annual)	Government
Cost	Pathology: \$2,087,750 Diagnostic imaging: \$8,852,900 Total: \$10,940,650 (Year 1) Costs are expected to be incurred by pathology and diagnostic imaging providers that do not yet have My Health Record conformant software for uploading.	Nil Changes due to the mandate will incur nil costs as there is no additional impost on consumers.	Nil/negligible The option to mandate share by default will not directly impose requirements. However, initial expenses and resource allocation difficulties may be encountered when training staff and implementing new data-sharing protocols.	Implementation: compliance, extensions and communication and education activities: \$5m (Two-year total spend) Note: these are estimates and would be subject to future decisions of the Australian Government. To ensure pathology and diagnostic imaging providers comply with upload legislative requirements, it is expected costs will be incurred to support the compliance and extensions activities, and communication and education.

Economic benefits: Option 1

Efficient healthcare delivery: requiring the sharing of pathology and diagnostic imaging information to My Health Record offers substantial economic benefits. By reducing the duplication of tests, it leads to long-term cost savings and promotes more efficient healthcare delivery. Healthcare providers can avoid unnecessary repeat tests, saving resources and reducing overall healthcare expenditure.

Improved productivity: providers would spend less time gathering patient information from disparate sources, providing potentially significant benefits in time to focus on patient care. This streamlined access to information enhances workflow efficiency and reduces administrative burdens.

Reduction in healthcare costs: there would be a potential reduction in costs due to fewer medical errors and improved patient outcomes. Comprehensive and accurate patient records help in making informed clinical decisions, reducing the likelihood of errors and adverse events. This not only improves patient safety but also leads to better health outcomes, lowering the costs associated with managing complications and long-term care.

Economic costs: Option 1

Initial investment in infrastructure and resources: this would include training, and system upgrades to support mandatory data sharing where not already registered as a participant in My Health Record, particularly for small providers.

Transitional challenges: there may be potential temporary challenges experienced by providers during the initial transition period which may cause disruption to services as providers adapt to new requirements.

Loss of billing opportunities for providers: with greater access to healthcare results, healthcare providers may see a reduction in consumers requiring follow-up appointments to learn or discuss their results. This reduction in follow-up appointments may be considered as a loss of billing opportunities for healthcare practices. The flow on impact of a reduction in duplicate testing may be that pathology and diagnostic imaging providers also see a reduction in the number of requests for diagnostics services.

Financial burden: integrating the new system requires a substantial financial investment from pathology and diagnostic imaging providers, including costs for new technology, staff training, system upgrades, and managing initial administrative inefficiencies.

Increased costs for successful implementation: achieving widespread adoption and public acceptance requires comprehensive planning and additional funding initiatives to drive adoption and develop enabling conditions. This may include costs beyond the current budget, such as additional policy development, technology maintenance and system upgrades.

Reduced revenue because of reduced testing: a reduction in duplicate testing could lead to decreased revenue for pathology and diagnostic imaging providers. This reduction in testing volume could directly impact their financial performance and sustainability.

Social benefits: Option 1

Enhanced quality of care: a more coordinated comprehensive approach to health records will lead to better health outcomes and opportunity for improved patient satisfaction. When healthcare providers have access to complete patient information, they can make more informed decisions resulting in more accurate diagnoses and effective treatments.

Increased consumer trust: as patients experience more coordinated and effective care, increased trust in the health system is fostered. The transparency and accessibility of health information empowers patients, giving them greater control over their health and fostering a sense of involvement in their care. These social benefits underscore the importance of integrating pathology and diagnostic imaging information into My Health Record, ultimately contributing to a more patient-centred and trustworthy health system.

Social costs: Option 1

Increased workload for healthcare providers: adapting workflows to manage mandatory sharing and exception processes might cause additional and ongoing burden. There may be an increased workload for healthcare providers due to the need to manage consumer misinterpretation of results, increased demand for appointments and enquiries by consumers seeking an explanation of their results, and increased demand for emergency services where consumers cannot see their referring healthcare provider and are worried about their results.

Privacy Concerns: there may be concerns among consumers about the security and privacy of their health information, potentially leading to apprehension about data sharing. While this data is already uploaded to My Health Record, because there will be increased volumes of data there are potential anxieties about data security and unauthorised access. This may require continued attention to robust safeguards and clear communication on how risks are managed and monitored. Sharing by default may also increase risks for vulnerable consumers, such as victims of family violence or people who are stigmatised. Further detail regarding My Health Record security and privacy safeguards can be found on page 11 to 12.

Consumer misinterpretation: consumers may misinterpret their health results, leading to distress or loss of follow-up care. Some providers are concerned about associated medico-legal implications.

Ethical and safety considerations: consultation feedback highlighted the need to recognise that upload should be withheld in some circumstances to ensure patient safety. Appropriate risk mitigation strategies may be explored for implementation to ensure the mandate can be realised as safely as possible.

Digital access barriers: it is acknowledged that while there are net benefits to improving access and sharing of health information through uploading reports to My Health Record, not all consumers may benefit due to digital access barriers. This may lead to experiencing a reduction in benefits like better healthcare engagement and increased health management responsibility. Those with limited digital literacy or resource access may have reduced benefits like better healthcare engagement and increased health management responsibility.

Environmental benefits: Option 1

Reduction in consumption of physical resources: Reducing duplicate tests saves physical resources like paper and ink, and minimises the use of essential testing equipment and products, such as syringes, specimen collection tubes, needles, reducing overall waste. This reduction in resource use helps decrease deforestation and waste.

Fewer repeat tests mean less energy consumption from running diagnostic machines and laboratory equipment, which are typically energy-intensive leading to a lower overall carbon footprint for the healthcare sector. Travel for patients and healthcare providers can also be minimised solely to transfer or access medical records, reducing carbon emissions to contribute to a more sustainable and eco-friendlier health system.

Environmental costs: Option 1

Option 1 has minimal direct environmental costs, primarily related to the digital nature of the data.

Net benefit Option 2 – Maintain the status quo (no change)

Overview

Under the status quo, sharing by default to My Health Record will not be implemented. The uptake levels of information shared to My Health Record will be dependent on healthcare providers voluntarily uploading information which risks stagnation or even decline with no active mechanisms requiring providers to upload information.

This option minimises the regulatory burden on pathology and diagnostic imaging providers to upload, avoiding the need for software changes and an increase of uploading. However, the lack of change may exacerbate downstream impacts to healthcare delivery, sustainability practices, and resource use. This poses significant risks, including continued fragmentation of health data, reduced efficiency in patient care, and potential delays in diagnosis and treatment due to lack of readily available information.

While this option would minimise regulatory impost for industry stakeholders, the associated cost, time and sustainability impacts outweigh any benefit.

Who is affected and what are the economic, social and environmental costs and benefits?

The absence of change to promote health information sharing to My Health Record will continue to impact healthcare for consumers, providers, and care coordinators alike. While industry stakeholders may avoid changes in their regulatory and operational landscape, the increasing need for readily available and accessible health information will continue to persist across the health sector.

Pathology and diagnostic imaging providers

Administrative inefficiencies may continue for pathology and diagnostic imaging providers due to limited access and capacity to reconcile consumer information. Providers will need to manage and store patient data independently, thereby duplicating efforts, increasing paperwork, and leading to fragmented data management processes.

Providers may struggle with incomplete consumer records, leading to delays in accessing critical health information. This can hinder timely decision making and coordination of care, ultimately affecting the quality and efficiency of healthcare services provided to patients.

Impact on smaller pathology and diagnostic imaging providers

Smaller pathology and diagnostic imaging providers may benefit by not needing to adopt and utilise My Health Record conformant software for uploading results. However, a lack of incentive to conform may further limit their ability to compete with larger providers who may already have the resources to implement such systems. Consequently, smaller providers may struggle to maintain efficient operations and ensure continuity of care for their patients, potentially exacerbating existing inequalities in healthcare access and quality.

Health systems and administrators

Under the status quo, health systems and administrators will continue to experience disjointed processes. Without a reliable, secure and centralised system that reconciles key health information, there is a lack of standardised data integration. This fragmentation can lead to inefficiencies in managing patient information, complicating efforts to streamline operations and coordinate care across different providers and departments.

Maintaining the current approach results in unnecessary costs for health systems and administrators. Resources are spent on redundant data management systems and manual processes. These additional expenses could otherwise be allocated to improving consumer care and other critical areas within the health system. In **Table 9** below, the benefits and costs to pathology and diagnostic imaging providers are outlined under Option 2.

Table 9: Pathology and diagnostic imaging provider costs and benefits for maintaining status quo

Pathology and Diagnostic Imaging Provider			
Benefit	Pathology	Diagnostic imaging	
	\$0	\$0	
Cost	Nil		

Consumers

Consumers will continue to experience fragmentation with their health records, with vital health information potentially missing from My Health Record. This can lead to incomplete medical histories, complicating diagnosis and treatment planning.

Patients may face challenges in accessing comprehensive health information, which is crucial for making informed decisions about their care.

Incomplete records can result in medication errors, repeated testing and misdiagnoses, posing significant risks to patient safety. Consumers may also experience a decreased amount of service availability, with provider time consumed by repeat testing.

Consumers may incur higher healthcare costs due to unnecessary duplicate testing and prolonged time to diagnosis, as healthcare providers may not have access to previous test results. Consumer costs and benefits for maintaining status quo are outlined below in **Table 10**.

Impact to vulnerable populations

The absence of a mandate for pathology and diagnostic imaging providers to upload to My Health Record may have significant implications for vulnerable populations. These groups often rely heavily on consistent and coordinated healthcare services, and without mandated uploads their health information may not be readily available to all relevant providers. This can lead to fragmented care, where critical health information is missed or not communicated effectively resulting in delays in diagnosis and treatment. Vulnerable populations may also experience increased health disparities as a result, as their access to timely and comprehensive care could be compromised.

Consumer		
Benefit	Pathology \$0	Diagnostic imaging \$0
Cost	Nil	

Table 10: Consumer costs and benefits for maintaining status quo

Healthcare providers

Healthcare providers will continue to face inefficiencies in their workflows as they spend extra time gathering patient information from multiple sources. This can lead to delays in patient care and increased administrative burden.

Incomplete patient information can increase the likelihood of medical errors, as healthcare providers may not have access to a consumer's complete medical history, previous test results or current medications. The added burden of tracking down consumer information can contribute to healthcare provider frustration and burnout, negatively impacting job satisfaction and potentially contributing to turnover rates in the healthcare workforce.

Impact on smaller and geographically isolated healthcare providers

For smaller and geographically isolated healthcare providers, the lack of a mandated requirement to upload to My Health Record can pose unique challenges. These providers often face logistical and financial barriers to adopting new technologies and systems. Without a regulatory push, they may prioritise immediate operational needs over long-term digital health investments. As a result, these providers may miss out on the benefits of enhanced interoperability and information sharing that My Health Record could offer, limiting their ability to deliver coordinated care, especially for patients with complex health needs. This gap in technological adoption can further widen the disparities in healthcare access and quality for patients in remote or underserved areas.

Care coordination

Effective care coordination relies on the seamless exchange of accurate and timely health information. Without continuous and complete data sharing, care teams may struggle with incomplete or outdated patient information, hindering their ability to provide coordinated care.

The lack of a centralised, comprehensive health record can result in communication gaps between different healthcare providers involved in a patient's care. This can lead to fragmented care and overlooked critical health information.

Transitions of care, such as hospital discharges or referrals to specialists, may be less efficient and more prone to errors without a complete and up-to-date health record. This can delay appropriate follow-up care and adversely affect patient outcomes. Benefits and costs to pathology and diagnostic imaging providers under the status quo are outlined in **Table 11**.

Healthcare Providers		
Benefit	Pathology	Diagnostic imaging
	\$0	\$0
Cost	Nil	

Table 11: Healthcare provider costs and benefits for maintaining status quo

Government

Limited data availability affects the ability to analyse health trends, monitor public health outcomes, and develop evidence-based policies. This lack of comprehensive data can lead to decisions that are not fully informed by the current health landscape. Australian Government costs and benefits are outlined in **Table 12**.

Table 12: Government costs and benefits for maintaining status quo

Government		
Benefit	Pathology	Diagnostic imaging
	\$0	\$0
Cost	\$0	

Analysis of the net benefit of Option 2 – Maintain the status quo (no change)

Net benefit

The analysis indicates that maintaining the status quo presents a net negative impact overall. Fragmented health data can lead to inefficiencies, higher healthcare costs, potential medical errors, and delays in patient care. Furthermore, the environmental impact of continued repeated and redundant tests adds to the overall cost. Therefore, the net benefit of this option is limited, primarily preserving current inefficiencies and risks associated with incomplete health records. A summary of benefits and costs for Option 2 - Maintaining the status quo is outlined in **Table 13**.

	Pathology and diagnostic imaging providers	Consumers	Healthcare providers	Government
Benefit	Nil	Nil	Nil	Nil
Cost	Limited access to consumer information can lead to administrative inefficiencies, incomplete records, and delays in critical health information, ultimately affecting the quality and efficiency of healthcare services.	Fragmented health records can lead to incomplete medical histories, complicating diagnosis and treatment, increasing risks of medication errors and misdiagnoses, and resulting in higher healthcare costs due to unnecessary duplicate testing.	Healthcare providers will face workflow inefficiencies and increased administrative burdens due to fragmented patient information, leading to delays in care, higher risk of medical errors, and potential provider frustration and burnout.	Limited data availability hampers the future analysis of health trends, monitoring of public health outcomes, and development of evidence-based policies, leading to less informed decisions.

Table 13: Summary of costs and benefits for maintaining status quo

Economic costs: Option 2

Continued inefficiencies: maintaining the status quo could contribute to continued inefficiencies in the health system, resulting in potential increases in healthcare costs due to repeat testing and delayed treatments. In 2022–23, Australians accessed 196.9 million Medicare-subsidised pathology services, imaging scans and diagnostic services. Due to lack of information sharing, healthcare providers may order repeat tests, leading to unnecessary costs.

Delay in diagnosis and treatments: a lack of comprehensive health information can delay diagnoses and treatments, potentially resulting in more severe health issues and higher treatment costs. Furthermore, there is a potential loss of productivity as healthcare providers spend more time searching for consumer information from multiple sources.

Inconsistent, fragmented data management and security: costs related to managing and securing fragmented health data can also add to the economic burden. My Health Record operating in a Protected system provides a consistent layer of security conformance, protecting valuable consumer and healthcare provider information and potentially reducing financial losses from data breaches.

Increased health system set up and maintenance costs: potential savings for the health system are limited when continuing to operate without implementing new systems and processes required to support interoperability and reliable uploading of key health information. Healthcare providers could avoid the initial setup and ongoing maintenance costs associated with integrating their systems with My Health Record. This may be preferred for smaller providers that may lack the resources to comply with such requirements. Additionally, the flexibility allows providers to tailor their data-sharing practices to better meet the needs of their patients and practice. Balancing these factors is crucial for optimising both healthcare delivery and economic efficiency.

Social costs: Option 2

Impacts on health outcomes: when healthcare providers do not have access to comprehensive consumer information, it can lead to gaps in care, delayed diagnoses, and suboptimal treatment plans. An increased burden is placed on patients and their carers to manually maintain their records, often carrying physical copies of their test results. Consumers are required to remember their medical history, which can be cumbersome and prone to errors. Furthermore, the higher risk of medical errors and misdiagnosis due to fragmented, potentially delayed, information is a critical concern. Incomplete records can lead to incorrect treatments, adverse drug interactions, and other serious medical issues.

Environmental costs: Option 2

Increased use of resources: when healthcare providers do not have access to digital records, they often rely on physical copies of test results and medical records. This leads to higher consumption of materials, contributing to reduced sustainability practices due to increased waste. Additionally, the need to physically transport records between healthcare providers leads to higher carbon emissions and costs. The energy consumption associated with repeated tests, such as running diagnostic imaging machines and laboratory equipment, also adds to the environmental burden. For example, MRI machines and CT scanners are energy-intensive, and repeated use due to lack of information sharing can significantly increase their environmental footprint.

Question 5: Who did you consult and how did you incorporate their feedback?

Following the release of the Strengthening Medicare Taskforce Report in December 2022, the department, in partnership with the Agency, have undertaken a range of consultation activities. Views were sought through a variety of methods to enable stakeholders and the community to provide feedback in a way that supported their engagement needs where possible.

The department recognises the importance of consultation with a diverse range of stakeholders and perspectives to help inform the policy development process. The consultation activities undertaken have captured a broad range of views, from agreement to disagreement, and provided insights into the issues of greatest concern. The consultation feedback has influenced the policy development and design process and supported the continued engagement with key stakeholders over the last 12 months.

As mentioned, OCHE was consulted to provide input and feedback in the development of this Policy Impact Analysis. *High-level comments were provided on the approach to the policy impact assessment, however because of time constraints, not all feedback was able to be incorporated.* The engagement activities aimed to understand the diverse perspectives, experiences and knowledge of individuals and organisations, and in doing so utilise the insights gained to help shape the regulations, policies and support required to successfully deliver the initiatives.

The key themes identified in these consultations echo what was heard in previous consultation activities such as the Review of My Health Records Legislation and the Digital Health Blueprint 2023 – 2033, which at the core emphasise the need to improve information sharing and empower patient choice in care management.

Consultation

There were four key phases of consultation activities undertaken and described in this Policy Impact Analysis, which build on and are informed by progressive consultations undertaken through previous activities and initiatives (see pages 29-31). Further detail on consultation activities and a diagram of the consultation journey can be found in Appendix A.

Phase 1: Targeted consultation

In April to May 2023 the department consulted with eight key peak bodies and healthcare providers with an interest in health information shared by the pathology and diagnostic imaging sector:

- Australian Pathology
- Australian Diagnostic Imaging Association (ADIA)
- Public Pathology Australia
- Royal Australian and New Zealand College of Radiologists (RANZCR)
- The Royal College of Pathologists of Australia (RCPA)
- National Association of Testing Authorities (NATA)

- National Pathology Accreditation Advisory Council (NPAAC), and
- Australian Commission on Safety and Quality in Healthcare (ASQHC).

Discussions focused on how to significantly increase the uploading of pathology and diagnostic imaging reports to My Health Record by default. There was broad agreement that requiring sharing of diagnostic imaging and pathology reports to My Health Record can improve safety and quality in healthcare.

Phase 2: Public consultation

A national public consultation process was undertaken from 8 September to 31 October 2023 to seek feedback on the approach to implementing the requirement to upload pathology and diagnostic imaging reports to My Health Record by default, and removal of the seven-day consumer access delay.

How consultation was undertaken

The department undertook several methods to support respondents' participation according to their needs. Once released, the department sent individual letters to peak bodies, jurisdictions and consumer organisations inviting feedback and participation in the consultation process. Engagement through the Health social media platforms on Facebook, Instagram, LinkedIn and X were also utilised to encourage a diverse range of feedback. In addition, both a consumer and healthcare provider information webinar were provided in partnership with the Agency.

Stakeholders were provided the option to respond to as few or as many consultation questions as they wished. They were able to submit responses via the department's Consultation Hub or provide a direct response to a departmental email address.

Notification of the public consultation was distributed through existing stakeholder networks to ensure a broad reach across the community was achieved. The department's website was also updated to provide links to the consultation webpage.

A range of submissions were received from a broad group of individuals and organisations, including from vulnerable groups such as those from culturally and linguistically diverse backgrounds, Aboriginal and Torres Strait Islander peoples and communities, LGBTQIA+ and particularly marginalised and stigmatised groups such as those living with HIV, people experiencing domestic and family violence, and people living with complex and/or chronic disease and disability.

The public consultation explored questions around barriers, enablers, concerns and opportunities. A total of 416 submissions were received from a range of respondents including:

- consumers/individuals/patients/family members or carers of consumers (approximately half of the 416 submissions were received from this group)
- pathology services delivery providers
- diagnostic imaging service delivery providers
- other healthcare providers/practitioners (that is, not pathology and diagnostic imaging service providers)
- professional bodies/peak organisations, and
- state and territory government health departments/agencies.

Approximately half of the submissions were from respondents who identified as a consumer/individual/patient/family member or carer of a consumer. The submissions were reviewed to identify key themes and feedback. A summary report on the key themes and feedback from the public consultation along with submissions, where there was agreement to publish, were published on the department's <u>Consultation Hub</u> in May 2024.

Phase 3: Engagement with state and territory governments and key partner agencies

A work program with state and territory representatives commenced in February 2024 to confirm the scale and nature of the barriers and challenges that are preventing or impacting states and territories from being ready to share by default and identify the strategies to address them. Since February, the department, Agency and state and territory representatives have met on a regular bi-monthly cadence.

Further targeted consultation occurred in July 2024 with several states and territories to seek feedback on the draft scope of the sharing by default mandate to:

- ensure the proposed scope parameters will work effectively, and
- identify potential gaps.

Engagement with states and territories is occurring on a regular basis, including through established governance groups such as the Digital Health Oversight Committee, which reports to the Health Chief Executives Forum.

In addition, engagement has been occurring with the Office of the Australian Information Commissioner, as the regulator of the My Health Record system, and Services Australia, noting its role in supporting Medicare services and operating the Healthcare Identifier Service.

Phase 4: Engagement with the sector

Continuous sector engagement has been undertaken by the Agency since July 2023 to understand readiness to comply with the mandate and to identify other barriers/concerns that may need to be addressed as part of implementation. This includes engagement with:

- clinical peaks
- major pathology and diagnostic imaging providers
- software vendors
- jurisdictions, and
- through social media and communications.

The Agency is continuing to engage with the sector, including working with individual organisation and locations to support reducing any barriers they may have to be able to share to My Health Record.

Summary of consultation views

Concerns and misconceptions about the need for patient consent

There is a common misconception that healthcare providers need the patient's consent to upload their health information to My Health Record. This has not been the case since the change to the opt-out system¹. Stakeholders correctly noted that some state and territory laws require consent for certain public health information to be uploaded to My Health Record.

Concerns about clinical safety

Stakeholders broadly supported the uploading of pathology and diagnostic reports by default, however they raised concerns about the clinical safety for consumers and that implementation should consider mitigations including supporting easy to understand consumer information. These concerns mostly relate to the parallel work being undertaken which seeks to remove the seven-day delay for most diagnostic reports so consumers can see them in My Health Record. Stakeholder views expressed concern of the potential impact this removal may have on consumer wellbeing for example if they have access to their results before discussing them with their healthcare provider. Little research data is available to support these claims to assist the development of this Policy Impact Analysis.

However, the establishment of the Clinical Reference Group (see page 31) is in direct response to these concerns. The group is currently considering these stakeholder views and will provide advice and recommendations to the Program Control Group to support further policy development and implementation activities. Option 1 (see pages 41-43) outlines how this approach has taken into consideration consumer health, safety and wellbeing and the maintenance of existing clinical discretion.

Implementation issues and risks

As previously outlined, there is a limited number of providers who have stated they will not be working towards sharing by default without a legislative requirement for them to do so being in place, due to their desire to avoid or defer the associated impost on their organisations.

The views of some software vendors and pathology and diagnostic imaging providers are that financial incentives are also required in addition to a requirement to upload, in recognition of the additional resources and costs required to uplift their systems to be conformant with My Health Record.

¹ Except where a prescribed law of a state or territory requires consent to the disclosure of particular health information. These laws are prescribed in section 3.1.1 of the My Health Records Regulation 2012.

Agreement of the need to upload to My Health Record

Overall, there was general support and recognition of the benefits of introducing a requirement to share by default, noting a range of barriers, challenges, concerns and enablers. Most stakeholders agreed that there should be a requirement to improve health information being made available in My Health Record. They understood and commented on pathology and diagnostic reports being a good place to start. They mentioned the work already done by this sector to connect to My Health Record. They noted that the high rates of COVID-19 pathology reports uploaded and viewed by consumers and healthcare providers set a good precedent.

Tables 14, 15 and **16** provide a summary of stakeholder's views regarding areas of disagreement and potential risks, benefits and considerations for the department to support implementation. It does not include themes related to the removal of the seven-day consumer access delay policy although some views related to both the proposed mandate and the removal of the seven-day consumer access delay.

A summary report on the key themes and feedback from the public consultation is available on the <u>Consultation Hub</u>.

Areas of disagreement and potential risk	Summary of responses
Legislation and policies may prevent or impact sharing by default	Feedback identified that preserved privacy laws contribute to a lack of consistency and create confusion for both public and private providers, particularly those operating across state and territory borders.
Not all software is conformant or has the required functionality to enable sharing by default	Some systems only have functionality to 'turn on' to upload all reports without providing the ability to adhere to individual consumer requests. States and territories identified cost and resource constraints as barriers/challenges to establishing system interoperability and/or software conformance.
Implementation will have a financial and administrative impact	Feedback identified a concern that share by default would incur a range of implementation costs. Examples included initial and ongoing costs relating to conformant software for smaller and some medium size organisations, managing legacy systems in parallel with new systems and potential staff training costs.

Table 14: Areas of disagreement and potential risks identified by stakeholders which have informed Option 1

Areas of disagreement and potential risk	Summary of responses
Risks for vulnerable consumers	Feedback identified a concern that sharing by default may present specific risks for consumers who are vulnerable, marginalised or stigmatised, including those experiencing family or domestic violence.
	It was also noted that some people experience barriers that may impact their ability to understand information and make decisions that are relevant to sharing by default.
Ensure safeguards are in place for managing sensitive/abnormal/time- critical results	Feedback identified the importance of safeguards for managing sensitive/abnormal/time-critical results. It was noted that safeguards should include delaying upload of sensitive/abnormal results, notifying the referring healthcare provider if a consumer's result needs immediate attention to ensure appropriate follow up of abnormal/time-critical results.
Consumer safety and wellbeing concerns	One concern identified was if a consumer views their result/report/test prior to consulting with their clinician, they may misinterpret them and subsequently experience undue stress and anxiety, leading to a potential loss of follow up care. In contrast, some consumer feedback highlighted a preference and perceived benefit in consumers being able to receive feedback in their preferred environment.

Table 15: Benefits identified by stakeholders

Benefits identified	Summary of responses
Cost and time efficiencies for healthcare providers and the health system	Feedback identified that sharing by default results in cost and time efficiencies for healthcare providers and the health system.
Improved consumer engagement and ability to manage their health	Feedback identified that sharing by default will enable consumers to have better access to their health information. This benefit was amplified for consumers who travel to different locations for services, are reliant on specific providers of speciality care, or cross borders for services. Feedback identified that, by having better access to their health information, consumers can have more informed discussions with their healthcare providers, seek follow up care and was particularly beneficial for consumers with chronic and long-term conditions.

Benefits identified	Summary of responses
Improved care coordination and consumer outcomes	Feedback identified that sharing by default improves the availability of health information across settings (in both clinical and consumer contexts), with quick and easy access to key health information at the point of care.

Implementation considerations	Feedback
National consistency	Feedback reflected the need for national consistency in the approach to sharing by default coupled with the need for appropriate safeguards for safety and wellbeing considerations. Feedback also identified that legislation/regulations/policies should be harmonised, particularly those that relate to privacy and consent.
Standardise reporting, ensure accuracy and completeness of reports prior to upload, and determine how to handle preliminary reports	Feedback identified that reports should be accurate, complete and standardised to support interpretation, not only by consumers but also across healthcare providers.
Recognise that upload should be withheld or delayed in some circumstances	Feedback identified a need to recognise that results should not be uploaded or consumer access to results is delayed to My Health Record in some circumstances. It was noted that there should be test-based exceptions and safety and wellness exceptions to be exercised where healthcare providers are concerned for the safety or wellbeing of the consumer.
Implement specific communication and education activities for consumers	Feedback identified that activities should be implemented to support consumers to understand My Health Record and its functions and the changes to sharing pathology and diagnostic imaging reports to My Health Record by default. It was noted that communication and education activities for consumers should be easy to understand and accessible for all members of the community, including those with complex communication needs and those from culturally and linguistically diverse backgrounds.

Table 16: Ways to support effective implementation identified by stakeholders

Implementation considerations	Feedback	
Review and standardise reporting and support consumers to understand results and next steps	Feedback identified a need to review how reports are written to support consumers to understand results and next steps.	
Develop resources to support consumers to understand results and next steps	In addition to reviewing how reports are written, feedback identified a need to provide information to support consumers to understand results and next steps, such as providing links to reliable information, such as Pathology Tests Explained.	
Implement supporting communication and education activities	In addition to supporting consumers to understand results, feedback emphasised the need to implement broader supporting communication and education activities.	
Implement activities to support general awareness	Feedback identified that activities should be implemented to support general awareness of the changes to share pathology and diagnostic imaging reports to My Health Record by default.	
Provide funding to support implementation	Feedback called for funding to support implementation, particularly to enable consumer access to timely follow up support to discuss results.	

Limitations of consultation

Notification of the public consultation was distributed through existing stakeholder networks to ensure as broad a reach across the community was achieved. The department's website was also updated to provide links to the consultation webpage.

A range of submissions were received from a broad group of individuals and organisations including from vulnerable groups such as those who are:

- culturally and linguistically diverse
- Aboriginal and Torres Strait Islander peoples and communities
- LGBTQIA+
- marginalised and stigmatised groups such as those living with HIV
- people experiencing domestic and family violence
- people living with complex and/or chronic disease and disability.

It is noted that the question-and-answer format of the consultation process may not have captured the views of all affected groups across the community and if more time was available other forms of engagement could have been considered. Further consultation and engagement activities will continue to explore activities to capture a broad range of views to support implementation activities.

Some participants who identified with a particular stakeholder category were asked to answer an additional 10 questions. Some feedback identified survey fatigue and slight repetition in questioning. A balance between open-ended questions and targeted questions would have provided a counterbalance and less participation fatigue. An option for direct submissions to the department or feedback via the consultation hub catered to participation preferences.

The public consultation also did not require respondents to provide a sentiment for share by default. Rather, respondents were asked for considerations and existing barriers towards implementation.

How this feedback informed policy development

The policy development process has incorporated the extensive consultation outlined above with a wide variety of key stakeholders including healthcare provider peaks, pathology and diagnostic imaging providers, professional bodies, consumer and carers, and state and territory governments.

The establishment and design of the <u>Clinical Reference Group</u> (see page 31) responds to concerns raised through the Phase 1 Targeted Stakeholder and Phase 2 Public Consultation processes.

The Clinical Reference Group was established to provide clinical advice and strategic guidance on safety and quality matters, and ensure implementation is aligned with consumer needs and preferences and clinical workflows.

The Clinical Reference Group scope includes:

- directly considering the potential risks raised relating to consumer safety and wellbeing, such as consumer misinterpretation of results or low levels of healthcare provider engagement due to concerns for consumer safety
- advising on mitigation strategies for identified issues and risks
- providing feedback on the functionality of the My Health Record platform and my health app to support refinement of settings including any application of any delay to sharing by default
- education and communication for consumers, healthcare providers, carers and pathology and diagnostic imaging providers
- development of clinical support resources for healthcare providers and consumers, and
- advising on a monitoring and evaluation framework.

The Clinical Reference Group is co-chaired by senior representatives from the Agency and the Australian Commission on Safety and Quality in Healthcare. The group of 24 members include relevant peak bodies and professional organisations, stakeholders involved in pathology and diagnostic imaging services, and consumer and community leaders living with and representing communities of lived experience.

Consultation submissions from states and territories informed the establishment of Phase 3 consultation activities being a regular work program of bilateral discussions with states and territories (see page 77). Barriers and challenges to implementation identified in Phase 3 have supported program communications to the Program Control Group and Digital Health Oversight Committee and are informing the development of a communication and education plan.

The full spectrum of consultation responses forms a core element of continued implementation planning activities and are being utilised to formulate communication and education implementation for consumers, healthcare providers and software vendors over the coming months.

Question 6: What is the best option from those you have considered and how will it be implemented?

Identifying the preferred option

To identify a preferred Option, a decision rule to ascertain the option that best meets the objectives of the Australian Government includes the outcomes of the cost-benefit analysis and feedback received through consultation feedback.

Option 1 - will address the key objectives for increased availability of consumer health information. Whilst some stakeholder groups may incur initial cost and some additional regulatory burden, the Policy Impact Analysis identifies that it is more likely to be effective in achieving the earlier outlined objectives and achieving the greatest net benefit, making it the preferred option.

Option 2 - retains the status quo and will not fully address the problem of lack of consistent access to health information. Although some progress has been made, it is unlikely that this momentum will continue, and as previous initiatives (as mentioned above) have shown, lack of consistent buy-in will likely result in a stagnation in health information being shared.

Best option and net benefits

The department considers Option 1 – requiring the uploading of pathology and diagnostic imaging reports – the best option for delivering optimum health outcomes and to provide the best net-benefit to Australians and to the broader health system. This option ensures consumers' My Health Record contains the most complete pathology and diagnostic imaging records to support clinical care and the sharing of health information with healthcare providers and the consumer. The rationale for this position is:

- The Australian Government has already invested in the My Health Record system, resulting in a zero-sum cost for this aspect of the preferred option.
- A significant proportion of diagnostic imaging and pathology providers are already connected to My Health Record and therefore the net impact on these businesses may be limited to the administrative impost of uploading a greater volume.
- The overall long-term benefits to the health system and clinical care of consumers outweigh the short-term costs to industry. A secondary benefit is that all entities will be required to comply with My Health Record standards, thereby improving their own interoperability capability to connect with other national systems. Connection to My Health Record may also uplift the sector by placing data breach notification requirements on participants and requiring cyber security policies to be in place. There are several intangible benefits to improving the security of health information across all businesses in the sector.

Implementation

To achieve success, Option 1 will be influenced by programs delivered at all levels of the Australian Government. The implementation of Option 1 will complement and align with the broader Australian Government measures under recommendations made by the Strengthening Medicare Taskforce (see page 14). The proposed measures outlined in this Policy Impact Analysis may complement existing and future measures.

This option may be implemented through a range of mechanisms, see **Table 17**.

Implementation	Responsibilities/governance	Potential risk
Engagement with the targeted sector to construct a legal and technical framework.	 This includes initial consultation on the proposal with industry and the public. Ongoing engagement with the affected sector to balance regulatory burden with policy objectives. 	 Timing to allow for considered engagement Lack of diversity in engagement
Legislative change (as described in previous sections) to mandate through legislation.	 Conduct a privacy impact assessment to ensure compliance with Commonwealth obligations. 	 Delayed legislative approval Bill does not pass
Introduction and enforcement arrangements. The legislative framework will provide for exemptions and delays for eligible healthcare providers to become conformant with the technical requirements to enable registration as a participant in the My Health Record system.	 Regulations will not come into force until six months after the Bill commences. Extension processes will be available to be registered or uploaded. Compliance and enforcement provisions will come into effect at the same time. Exemptions will be outlined in regulations. 	 Provider confusion as to what the obligations are that they need to comply with.

Table 17: Option 1 implementation, responsibilities/governance and potential risks

Implementation	Implementation Responsibilities/governance	
Establishment of a time- limited clinical reference group to provide advice on clinical workflow and patient-centred care implications.	• The Agency's standing clinical advisory committee will provide advice as required on the ongoing delivery of the program.	• Nil/negligible
Program assurance and evaluation to inform management of the requirement, design and implementation of any new requirements for other healthcare providers, and information to be prescribed under the framework.	 The Agency can monitor uploads and system views and collects data to help assess the impact on use. A post-implementation survey will be undertaken of primary care providers and consumers to ascertain views on changes to the availability of data and the impact on clinical care, including the decisions about making pathology and diagnostic referrals. 	• Nil/negligible
A compliance program to monitor uploading and compliance with requirements, including a post-implementation review as per the Australian Government Guide to Policy Impact Analysis.	The department's internal compliance team will partner with the Agency to collect relevant meta-data to determine provider compliance.	• Nil/negligible
Education program to explain the changes to healthcare providers and the public.	 This includes reminders about the My Health Record consent and authorisation framework. Advice about exception arrangements, where the healthcare provider or consumer determine that information should not be made available to My Health Record. Information on other administrative arrangements such as record keeping. 	Preparation of resources being available in time, including pre- implementation education.

What is the timing for implementation of Option 1?

Timing of the implementation of Option 1 is contingent on the passing of the Bill in parliament to enable legislative change. Due to this, timeframes for the implementation of points 2-7 (see **Table 17** above) are unable to be listed at this stage. Work is progressing in the meantime on these stages to ensure there are no delays once the Bill has been passed.

Implementation monitoring of core areas may be undertaken based on monthly My Health Record statistics from the Agency, including:

- upload rates by pathology and diagnostic imaging providers to My Health Record
- viewing rates of documents in My Health Record by healthcare providers, and
- viewing rates of documents in My Health Record by consumers.

This data will support monitoring of behaviour change in relation to the Objectives and will be able to be compared to high-level summaries of Medicare benefits data to understand trends in behaviour change.

Baseline data will be identified prior to and post implementation for key activities such as the enactment of legislation and education and communication targets towards consumers, healthcare providers, software vendors and pathology and diagnostic imaging providers.

It is expected that implementation baseline data will be regularly monitored in the first two years. Ongoing monitoring and evaluation may be considered by the relevant governance arrangements noting the likely development of technical capabilities and My Health Record system data available may expand during this period and will need to be considered to form a longer-term approach.

Implementation issues and risks

The following issues and risks have been identified for the implementation of Option 1:

- tight timeframes
- risk of the Bill not being passed or delayed in Parliament
- stakeholder dissatisfaction or lack of engagement
- availability of communication and education resources, and
- ensuring legislative change addresses policy problem.

Question 7. How will you evaluate your chosen option against the success metrics?

Monitoring and evaluation approach for the share by default mandate

To ensure the success of the implementation for the requirement to share to My Health Record by default for consumers and healthcare providers, including pathology and diagnostic imaging providers, a comprehensive monitoring and evaluation plan will be developed and implemented. This plan will be developed in line with the Commonwealth Evaluation Policy which provides for a principles-based evaluation approach that is fit-for-purpose, useful, robust, ethical, culturally appropriate, credible, and transparent where appropriate.

Specifically, the monitoring and evaluation approach will monitor and assess the mandate's performance against the outlined Objectives for Option 1, focusing on consumer empowerment, improved care coordination, and enhanced clinical decision making.

The approach taken will ensure ethical considerations by maintaining transparency, obtaining informed consent, and safeguarding patient confidentiality when sharing pathology and diagnostic imaging results to My Health Record. Additionally, it will respect cultural diversity by using culturally sensitive approaches and actively involving local communities to understand and address their specific needs and concerns.

As data becomes available, this will allow the evaluation framework to grow and evolve. Over time it is planned that information relating to specific metrics such as, but not limited to, rural and remote, culturally and linguistically diverse, and people living with complex and chronic health conditions will inform the outcomes for this policy. The growing of the evaluation framework may also support planning and implementation of future sharing by default policy changes.

The evaluation will consist of both process and outcome evaluations to ensure that the policy is not only implemented effectively but also achieves its intended objectives. Key metrics and data sources will be identified to track progress over time.

Oversight mechanisms and governance

A commonwealth mechanism to oversee this commonwealth initiative will be required with consideration given to existing governance structures to fulfill this function.

The existing governance structures which are supporting the planning for implementation of Option 1 include:

• The Program Control Group, which is co-chaired by the department and the Agency and meets monthly to oversight implementation considerations.

- The Program Working Group, which meets weekly to oversight implementation deliverables.
- The Clinical Reference Group, which is co-chaired by the Agency and the Australian Commission for Quality and Safety in Healthcare and meets approximately bi-monthly to provide strategic advice and clinical guidance for implementation.
- The Digital Health Oversight Committee (DHOC), which is established under the IGA on National Digital Health 2023-2027. The Commonwealth and all states and territories are represented on the committee which provides national coordination and strategic advice on digital health matters, including national digital health initiatives. The committee membership also includes representation from the Agency, Services Australia, and HealthDirect Australia as delivery partners.
- The Health Chief Executives Forum, which the DHOC reports to and is required to provide a work plan to this forum to ensure transparency and accountability in its operations and to ensure alignment with priorities set by the National Cabinet and the Health Ministers Meeting.

Rollout phase monitoring and evaluation

First 12 – 18 months

This phase focuses on the first 12-18 months from the enactment of legislative amendments. Real-time tracking on a monthly basis and assessment of compliance with the requirement to upload by default ensures that any trends or issues are quickly identified and addressed. This proactive approach allows for immediate corrective actions, thereby minimising disruptions and ensuring that the requirement to upload is implemented as intended. Monitoring during this phase is crucial for stakeholders, particularly pathology and diagnostic imaging providers, as it ensures that their operations can adapt smoothly to the new requirements without compromising service delivery.

Privacy Impact Assessment and risk mitigation strategies

A comprehensive Privacy Impact Assessment (PIA) was conducted to evaluate the policy against the Australian Privacy Principles (APPs). This assessment aimed to identify and mitigate potential risks associated with data collection and usage within the My Health Record System. Strategies were outlined to address key risks such as unauthorised access, data breaches, and misuse of personal information. These strategies will be further developed and refined during the implementation of the mandate.

During the evaluation and monitoring phases, data will be collected and managed in strict accordance with the outlined risk mitigation strategies. This includes implementing advanced encryption methods for data storage and transmission, conducting regular security audits, and ensuring that access controls are robust and up to date. Additionally, continuous monitoring will be employed to detect and respond to any potential security threats promptly. These measures will ensure that personal health information remains secure, and that the system operates transparently and efficiently to reinforce consumer confidence in the My Health Record System.

Data collection and sources

This will involve systematically gathering relevant data to track the implementation of Option 1. Key data sources include My Health Record usage statistics provided by the Agency, along with feedback and complaints from consumers and healthcare providers. Accurate and timely data collection is critical for identifying early trends and potential issues during the rollout phase. **Table 18** outlines the data and data sources to monitor and evaluate the rollout phase of implementation.

Outcome	Description	Responsible
Implementation metrics	 Monitor the implementation process through healthcare statistics from the Agency. Key metrics will include provider use of My Health Record conformant software, any technical issues encountered, volume of consumer contacts to the My Health Record helpline and the effectiveness of training programs for staff. 	The Agency to provide statistics from the My Health Record system undertaken as part of monthly monitoring. The department to support trend identification to support strategic policy development.
Consumer access and engagement	 Track the number of consumers accessing their pathology and diagnostic imaging reports through My Health Record. This data will be collected from My Health Record system analytics, focusing on user logins, report views, and the frequency of report sharing. 	The Agency to provide statistics from the My Health Record system undertaken as part of monthly monitoring.
Healthcare provider usage	 Measure the frequency with which healthcare providers access pathology and diagnostic imaging reports at the point of care. This will be monitored through system logs and surveys of healthcare providers to assess their experience with the new system. 	The Agency to provide statistics from the My Health Record system undertaken as part of monthly monitoring.

Table 18: Evaluation data and sources for rollout phase of implementation.

Outcome	Description	Responsible
Consumer feedback and satisfaction	• Collect feedback from consumers regarding their satisfaction with accessing and controlling their health information. This will include, surveys, focus groups, and user experience research to understand how consumers perceive their engagement and empowerment.	The Agency to undertake targeted consumer engagement.

Success metrics and benchmarks

Success metrics are predefined indicators used to measure the achievement of the mandate's objectives. Benchmarks are specific targets or standards against which progress can be compared. This sub-area ensures that the mandate is meeting its intended goals during implementation, such as the number of reports successfully uploaded to My Health Record and the level of consumer engagement.

Specific quantitative benchmarks and targets will be determined once a clear understanding of the baseline data is determined over the first 12-18 months of monitoring. This can only occur after the mandate is implemented and compliance and exemption frameworks are defined. Implementation benchmarks and success metrics are outlined in **Table 19**.

Benchmark/ success indicator	Metric	Description	Responsible
Consumer empowerment	Increase in percentage of consumers who actively access and manage their health information through My Health Record.	Success will be measured by the increase in consumer engagement. A significant increase from the baseline will indicate success.	The Agency in conjunction with the department

Benchmark/ success indicator	Metric	Description	Responsible
Improved care coordination	Measurement of healthcare provider access to diagnostic information.	Evaluate the extent to which healthcare providers report enhanced care coordination due to real-time access to diagnostic information. This will be benchmarked against pre-mandate levels of care coordination as reported in provider survey.	The Agency in conjunction with the department
Enhanced clinical decision making	Reduced diagnostic errors, faster treatment times, and higher provider satisfaction with available health information.	Success will be evaluated by reported improvement in clinical decision-making processes by healthcare providers and the monitoring of Medicare benefits data in comparison to upload and healthcare provider viewing rates for My Health Record.	The Agency in conjunction with the department

Post implementation evaluation

Six months post rollout

Post-rollout implementation evaluation is crucial for assessing the effects of the mandate once it has been enacted. This evaluation area focuses on analysing the initial outcomes to determine if the mandate has begun to meet its intended objectives and that implementation activities are having the desired impact.

Effective post-implementation evaluation will include:

- comparing baseline data with new data to identify any early changes in behaviour or outcomes. This phase may indicate whether the policy is on track to deliver its promised benefits and highlight any necessary adjustments
- assessing the effectiveness of education and communication activities', and
- utilising learning to support expansion of the digital health Benefits Framework and associated Benefits Register.

Effectiveness evaluation

There is a need to assess whether the mandate has achieved its intended outcomes once fully implemented. This assessment will evaluate the policy's impact on empowering consumers, improving care coordination, and supporting clinical decision making. The evaluation considers both qualitative and quantitative data, such as user satisfaction surveys and clinical outcomes as seen in **Table 20**.

Benchmark/ success indicator	Metric	Description
Consumer health outcomes	Trends in patient recovery rates, reduced hospital readmissions, reduced testing, and overall satisfaction with care as reported by consumers.	Assess whether the mandate has contributed to better health outcomes for consumers.
Healthcare provider efficiency	Reduced time spent in obtaining diagnostic information and increased time available for patient care.	Measure any improvements in healthcare provider efficiency. This will be supported by provider surveys and workflow analysis.
Cost-benefit analysis	Measurement of costs vs direct and indirect savings from improved health outcomes.	Conduct a detailed cost-benefit analysis to determine if the policy has resulted in financial savings for the health system.

Differential impacts

This aspect examines how the mandate affects different groups within the population, ensuring that it does not inadvertently disadvantage certain cohorts. For example, it looks at whether consumers in rural areas experience the same benefits as those in urban centres, or if certain healthcare providers face unique challenges. This evaluation helps identify and address any unintended consequences. These impacts are described in **Table 21** below.

Table 21: Evaluating impacts across consumer groups and healthcare providers
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Outcome	Description
Impact on different consumer groups	Evaluate whether the policy has had differential impacts on various consumer cohorts, such as older adults, those with chronic conditions, or rural populations. This will involve disaggregated data analysis to identify any disparities in outcomes.
Impact on healthcare providers	Assess whether the policy has placed additional burdens on certain types of healthcare providers, such as small practices or those in rural areas. This will be done through targeted surveys and interviews.

Ongoing monitoring and review

Ongoing monitoring and review will occur to ensure that the mandate continues to meet the Objectives over time and adapts to changing circumstances. This evaluation area is prioritised to provide continuous feedback on the policy's performance, allowing for timely adjustments to improve or sustain its effectiveness.

For different stakeholder groups, ongoing monitoring will mean that their needs and concerns are continuously addressed, and the mandate evolves in response to real-world challenges and opportunities.

An established enduring clinical governance approach will provide additional oversight of ongoing monitoring and evaluation. This approach is currently in the early stages of development with the details of membership, scope and frequency of meetings yet to be determined. It is intended that an enduring approach will however have both public and private provider representation.

Continuous improvement

This focuses on using the data collected from ongoing monitoring to make iterative improvements to the mandate. It ensures that the policy remains responsive to changes in the healthcare environment and continues to meet the needs of stakeholders over time. Continuous improvement helps maintain the relevance and effectiveness of the mandate. Approaches to undertake continuous improvement reviews and monitoring are outlined in **Table 22** below.

Table 22: Continuous improvement through periodic reviews and monitoring

Outcome	Description
Periodic reviews	The policy may undergo periodic reviews to assess its continued relevance and effectiveness considering changing healthcare technologies, consumer preferences, and industry standards. These reviews could involve stakeholder consultations and updated data analysis.
Accumulation of burden	Monitor the potential accumulation of burden on healthcare providers or specific consumer groups. If new regulations or changes in the healthcare environment create additional challenges, the policy will be reassessed to ensure it remains effective and not unnecessarily burdensome.

Reporting and accountability

This will involve reporting on the mandate's performance to relevant stakeholders, including Australian government bodies and the public. It ensures transparency and holds those responsible for the mandate accountable for its outcomes. Clear reporting structures and accountability mechanisms help build trust among consumers and healthcare providers while ensuring that the mandate remains aligned with its original Objectives.

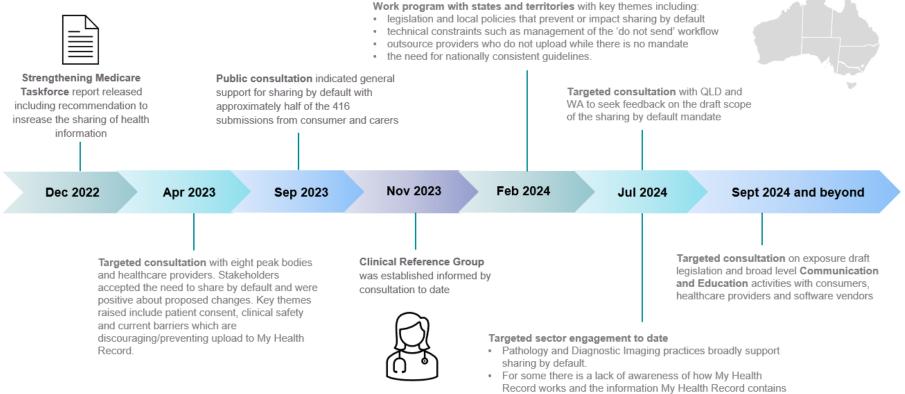
Enduring governance arrangements will be considered over the coming 12 months with consideration of the growth of the Evaluation Framework and maintaining a sustainable approach across the range of digital health initiatives. In **Table 23** below, activities are described for regular reporting and for the use of stakeholder feedback for evaluation.

Outcome	Description
Regular reporting	Findings from the evaluation will be reported to relevant stakeholders, including healthcare providers, consumer advocacy groups, and Australian government bodies. Reports will be published annually to ensure transparency and accountability.
Stakeholder feedback	Stakeholder feedback will be continually sought and integrated into the evaluation process, ensuring that the policy remains responsive to the needs of consumers and healthcare providers alike.

Table 23: Use of findings from reporting and feedback for evaluation

Appendices

Appendix A – Consultation journey



- The radiology sector believes facilitating access to diagnostic images would be of more value than reports.
- All diagnostic service providers are seeking clarity on timing of the reform coming into place.

Status of the Policy Impact Analysis at each major decision point

Decision point/point in policy development	Timeframe	Status of the Policy Impact Analysis
Australian Government announces funding in the 2023- 24 Budget to commence work to improve sharing to My Health Record commencing with requiring uploading of pathology and diagnostic imaging reports	May 2023	Undeveloped
Targeted consultation with 8eight key stakeholder groups	April - May 2023	Undeveloped
Public consultation with stakeholders	September – October 2023	Data collection commenced to support implementation planning and identification of benefits and disbenefits
Clinical Reference Group established	November 2023	Early advice supporting considerations of consumer health, safety and wellbeing in relation to the problem definition and benefits and risk mitigation considerations
Health Ministers agree to support the sharing of pathology and diagnostic imaging reports to My Health Record by identifying and overcoming barriers to sharing by default by December 2024	November 2023	Commitment informed consultation program of work with states and territories
Work program with states and territories commenced to support readiness to share by default	February 2024	Informed barriers and challenges for policy design and implementation
External consultant engaged to support development of Theory of change, Value mapping of benefits and disbenefits and Benefits Register to support cost benefit analysis	May 2024	Draft Policy Impact Analysis informed the development of deliverables

Australian Government announced additional funding in the 2024-25 Budget to support education and communication activities	May 2024	Informed communication and education activities to support policy development
Digital Health Oversight Committee members agreed to support the development and in-principle agreement to adopt nationally consistent clinical guidelines	June 2024	Informed implementation planning and utilised earlier consultation feedback which outline the need for national consistency to reduce confusion of existing various requirements at a national, state and territory and local area level for public and private providers
First Pass Assessment by OIA	October 2024	Policy Impact Analysis First Pass assessment completed
Second Pass Final Assessment by OIA	November 2024	Policy Impact Analysis presented to OIA for Second Pass Final Assessment

Appendix B – Assumptions and regulatory burden measurement framework

The regulatory burden measurements are calculated on a 10-year basis. As per the guidelines of the Office of Impact Analysis, costs are presented on an average per year basis, with one tenth of the initial start-up costs added to the expected ongoing annual regulatory burden costs to provide the annual average cost that is expected for the first ten years of the proposed regulation. A range of assumptions have been used as model inputs. Many of the key assumptions are the same between the measures, with a few variations.

Duplicate requests

Duplicate requesting can occur for a range of reasons, including that healthcare providers considering requesting testing at the point of care are unaware of or unable to access tests requested by other healthcare providers in a timely manner.

Duplicate requests for pathology and diagnostic imaging services cannot be directly measured with available information.

Based on a literature review, duplication in pathology and diagnostic imaging testing is estimated to be 5% of MBS services.

The following groups of tests are duplicated annually (excluding tests typically used by specialist health providers to diagnose, manage or monitor less common health conditions):

Diagnostic imaging

- I1 UltrasoundI2 Computerised tomography
- I3 Diagnostic radiology

Other diagnostic imaging groups are out of scope

Pathology

- P1 Haematology
- P2 Chemical
- P3 Microbiology
- P4 Immunology
- P10 Patient episode initiation
- P13 Bulk billing incentive

Other pathology groups are out of scope.

Exceptions to uploading

Upload rates will not occur where an exception is applied:

- The consumer does not have a My Health Record.
- The consumer has expressly requested a report not be uploaded to their My Health Record.
- The healthcare provider, pathologist or radiologist requests upload does not occur due to concerns for the consumers health, safety or wellbeing.
- Technical issues prevent upload (i.e. unable to match Healthcare Identifiers).

In addition to the number of consumers who do not have a My Health Record it is estimated that up to 10% of relevant diagnostic imaging and pathology reports may be exempt due to an exception being applied.

It is therefore estimated that up to 80% of diagnostic imaging and pathology reports would meet criteria requiring uploading to a consumer My Health Record.

Provider capacity to upload

Providers' capacity to commence uploading by default will vary. It is intended there will be a grace period following the proposed establishment of a requirement to upload. This will enable providers who do not have My Health Record conformant software to uplift to conformant software, train staff and amend policies and procedures.

Savings assume growth from current baseline of uploading. The Agency has provided advice on the potential achievable increase in uploading rates, which have been incorporated into the model.

Seven organisations account for approximately 98% of pathology services and have capacity to transition to uploading by default.

The Agency forecasts that most of the pathology sector could transition to uploading by default within one year, using current upload rates as a baseline.

Approximately 130 providers account for approximately 98% of MBS funded diagnostic imaging services and approximately 120 of these providers currently use My Health Record conformant software.

The Agency forecasts that most of the diagnostic imaging sector could transition to uploading by default within two years, using current upload rates as a baseline.

Healthcare provider viewing

It will take time for healthcare providers to develop confidence that My Health Record will be a reliable source of key health information and to routinely check a patient's My Health Record before requesting routine diagnostic investigations.

The Agency has provided advice on potential achievable growth in viewing rates, which has been incorporated into this model.

Agency data on upload and clinician viewing rates demonstrates a positive correlated relationship between the volume of reports uploaded and an increase in clinician viewing behaviours.

It is estimated that viewing rates could grow by 30% from current baseline rates for both diagnostic imaging and pathology.

The model assumes that when a health practitioner reviews a patient My Health Record and finds relevant reports, they may still opt to order a new diagnostic investigation.

A rapid review of literature shows that access to health information has had varying impacts on reducing duplicate requesting in primary care settings.

The measure includes a trial of communication strategies to raise awareness and prompt behaviour change.

The model includes an estimate that 50% of instances in which a healthcare provider views a patient record and identifies a relevant report that has been uploaded, a decision will be made not to request.

It is expected that evaluation of the early implementation of this measure will provide data to establish a more robust baseline and predictions, which can be incorporated into a future Budget comeback.

It is intended that uploading requirements also be applied to services not funded through MBS (including hospital services). Savings outside of Medicare are not being considered in this proposal.

FY 2023/24 will be consultation and development of supporting communications or tools necessary to support implementation. No impact on MBS costs is anticipated or modelled in this FY.

FY 2024/25 activities will enable voluntary transition and adoption of uploading by default, signalling that mandatory requirements will be introduced and enforced.

Other assumptions

The Agency is currently establishing improved data analytics capability, which will improve how uploading and viewing data is reported in the future. This data is not currently available but will be leveraged for evaluation and future benefits modelling activities.

Evaluation of the first tranches of implementation will inform the expansion of uploading requirements to other key health information in the future

by providing robust evidence of the effectiveness of different implementation approaches and potential costs and benefits of sharing by default.

Communication with consumers and healthcare providers who routinely request pathology or diagnostic imaging (e.g. GPs), encouraging them to review a patient's My Health Record before requesting an investigation, will strengthen the impact of the preferred policy option.

Progressive mandates to upload content to My Heath Record will drive healthcare provider demand for more seamless access to My Health Record via their clinical information systems.

To remain competitive in the market, software vendors will need to improve the experience and usability of their products to better support the workflow needs and obligations of their users, particularly where uploading content to My Health Record is required.

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All information in this publication is correct as at (November) 2024

