



Statement of Intent

Regulatory functions of the Australian Digital Health Agency

21 January 2026

Background

The Australian Government has identified better regulation as a key driver in boosting Australia's productivity, improving economic resilience and reducing undue burdens on businesses and consumers.

This Statement of Intent (SOI) responds to the Statement of Expectations (SOE) provided to the Australian Digital Health Agency (the Agency) on 26 November 2025 by the Hon Mark Butler, MP, Minister for Health and Ageing and Minister for Disability and the National Disability Insurance Scheme. The SOI outlines how the Agency will undertake its regulatory functions to deliver on the Minister's expectations to achieve digital health innovation, boost health and care service efficiency and support sustainable systemic growth, in line with government priorities.

The SOE and SOI form part of the government's Regulatory Policy, Practice and Performance Framework (RPPP) and were prepared in accordance with the requirements of Resource Management Guide 128 – Regulator Performance (RMG-128).

Role and functions of the Agency

The Agency was established under the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 (the Agency Rule) and functions as the System Operator under the My Health Records Act 2012.

The Agency Rule sets out the Agency's core functions, including administration of My Health Record (and the 1800MEDICARE app), statutory functions as the System Operator. It also includes administration of a wide and growing range of other national services, such as the Healthcare Information Provider Service (HIPS), Provider Connect Australia (PCA), electronic prescribing, the Real Time Prescription Monitoring (RTPM) system, Clinical Learning Australia and, going forward, Health Connect Australia.

As the steward for digital enablement of Australia's health system, the Agency plays a lead role in the national effort to drive system-wide change, including through the [National Digital Health Strategy 2023-2028](#), which is delivered in close partnership with all Australian governments, Australian healthcare consumers and providers and digital health delivery partners, reflecting a shared commitment to health system reform.

The Agency works closely with the Department of Health, Disability and Ageing (DHDA) to operationalise legislation designed to improve the sharing of health information at the point of care to support improved decision-making and improve health outcomes for all Australians.

The Agency also undertakes complementary activities, including the development and delivery of standards that enable the national digital health work program and uplifting the digital literacy and cyber maturity of healthcare system participants.

Commitment to align with Resource Management Guide-128 and the Regulatory Policy Practice and Performance Framework

Best practice approach to fulfilling regulatory functions

The Agency is committed to fulfilling its statutory responsibilities in line with best practice. This includes ensuring regulatory activities minimise the regulatory burden on Australian healthcare consumers and businesses, a commitment to continuous improvement, risk-based approaches and collaboration with stakeholders and other Commonwealth regulators to drive efficiency and performance. Our activities and functions are guided by the

Clinical Governance Framework for Digital Health (CGF) to ensure clinical safety, quality and continuous improvement in the delivery of the tools, services and infrastructure we administer.

The Agency's regulatory activities are informed by data-driven decision making, based on risk-commensurate monitoring and quality assurance activities to promote compliance and assess adherence. These activities are supported by education and guidance to assist all participants to understand and meet their responsibilities and by proportionate action, where required, to protect the security and integrity of the My Health Record system.

The Agency undertakes routine performance reporting and shares information on progress openly and transparently. The SOE, along with the SOI, will be incorporated into this reporting, including the corporate plan and annual reporting processes.

Cyber security is a core investment priority. As new data pathways are enabled, the increased availability of health data, including associated administrative data and identifying data, reinforces the importance of safeguarding personal information and sensitive health information.

The Agency maintains a dedicated cyber security capability focused on security by design, governance, risk and compliance management, policy implementation, assurance testing, proactive cyber security monitoring, threat hunting and response and collation and dissemination of threat intelligence relevant to the Agency and the health system. Increasingly, the Agency is playing a greater role in supporting the uplift of cyber security awareness across the entire healthcare ecosystem to build a resilient digital health environment. These efforts align with Horizon 2 (2026–2028) of the Australian Cyber Security Strategy 2023–2030, which aims to scale cyber maturity across the economy.

Approach as digital health evolves

The evolution of digital health, including implementation of the Health Legislation Amendment (Modernising My Health Record—Sharing by Default) Act 2025, represents a significant shift in healthcare delivery. These changes provide a legislative framework for prescribing the healthcare information that must be uploaded to My Health Record and the healthcare providers required to upload. This will address gaps in consumers' records that have historically hampered care and will help modernise healthcare, delivering more timely and comprehensive information for providers and consumers alike.

Under the new framework for the first time My Health Record registration will be mandatory for prescribed healthcare providers. Over the next two years, the Agency will lead implementation of this new legislative regime by engaging and educating providers and vendors early, integrating changes with existing systems and providing targeted support.

The intention is to support safe connection to the greatest extent possible, to maximise the impact of the legislative change, providing Australians with their health information at their fingertips – a goal that must also be balanced with the need to ensure the safety and integrity of the system and the protection of Australians' critical health information.

The Agency's conformance activity is a key means of supporting the security, integrity and stability of connections and transactions across digital health products and services delivered by the Agency. In tandem with the CGF the Agency's Conformance Framework ensures these services are designed, developed and operated in a manner that is person-centred, safe and interoperable.

The Agency intends to leverage the share by default framework to enforce conformance and standards - driving interoperability and security across systems to improve care coordination and health outcomes while reducing administrative burden.

The share by default approach is also being implemented alongside the delivery of initiatives under the National Healthcare Interoperability Plan 2023–2028. Initiatives under this plan, like the expanded use of healthcare identifiers, coupled with adoption and use of digital health standards, will continue to support a more connected ecosystem, providing Australians with the ability to more easily share their data with and between healthcare providers and ensuring patients receive the most effective and informed care when needed.

The Agency will continue to use co-design approaches with Australian governments, consumers and carers, healthcare providers, the health technology sector and peak bodies to inform how we proceed and to consider the needs of key cohorts within the community, including First Nations people and communities, people living with disability, older Australians and LGBTIQ+ communities.

Relationship with government

The Agency will continue to support the Minister, the portfolio and broader government in carrying out its functions, including engaging with jurisdictions to leverage and harmonise digital health solutions. The Agency will also continue to keep the Minister informed with accurate and timely advice on significant issues in its core areas of business, particularly those that may impact the government's health reform agenda.

The Agency will continue to support DHDA on consultations with jurisdictions to enable secure and seamless information sharing through the harmonisation of legislation, policies and systems. Further, the Agency engages in global forums and works with standards organisations to align with international best practice where appropriate, building trust in its processes, identifying opportunities for innovation and supporting timely adoption of improved standards within international best practice frameworks.

Supporting broader government policies around productivity and growth

The Agency seeks to unlock productivity at a national scale by supporting a sustainable and interoperable health and care system that can meet the growing demands of Australians now and into the future.

Our principles-based compliance model has been applied to recent health reforms to reduce reporting duplication and increase information sharing and to streamline the processes necessary for compliance with the regulations.

- For example, sharing by default has already driven significant growth in the number of pathology and diagnostic imaging providers connecting into the My Health Record System as the sector prepares for registration and mandatory uploading, and a notable shift in consumer behaviour.
- Over time, share by default will be expanded beyond pathology and diagnostic imaging reports to include other key health information to further empower Australians and increase the availability of health data for users of the My Health Record system.

Enabling better and faster access to these reports will improve productivity in the healthcare sector and enhance clinical decision making, care coordination and overall health outcomes. It will also reduce the need for duplicate tests and the associated costs to healthcare consumers and the healthcare system. However, the Agency also considers the impact of these reforms on different stakeholders in implementation. For example, recognising that a substantial number of smaller businesses will need to connect with the My Health Record system to comply with the mandate, the Agency is implementing a simple online application process for prescribed healthcare providers needing an extension of time to become technically ready to upload.

Conclusion

The Agency will continue to mature its regulatory approach as part of the broader implementation of the national digital health modernisation program, ensuring it remains fit-for-purpose, proportionate and adaptable to emerging challenges and opportunities, supporting both public value and economic resilience.



Lyn McGrath
Chair
Australian Digital Health Agency Board
21 January 2026