Australian Government

Department of Health, Disability and Ageing

Statement of Intent

Introduction

This Statement of Intent (SOI) responds to the Statement of Expectations (SOE) signed on 18 December 2025 by Minister Butler, the Minister for Health and Ageing and the Minister for Disability and the NDIS. The SOI sets out how our departmental regulators intend to meet the Minister's expectations to achieve regulatory objectives and carry out regulatory functions.

Overview

The SOI forms part of the government's Regulatory Policy, Practice & Performance Framework (RPPPF) and was prepared in accordance with Resource Management Guide 128 - Regulator Performance (RMG-128).

The SOI covers the following eight departmental regulators and regulatory functions:

- Regulatory oversight of therapeutic goods
- Supporting access to subsidised hearing services
- Supporting access to pharmaceutical benefits
- Supporting the integrity of health benefit claims
- Regulatory oversight of private health insurance and private hospitals
- Regulating vaping goods (including e-cigarettes)
- Regulatory oversight of tobacco products, and
- Regulatory oversight of supports and services, outside of the National Disability Insurance Scheme (NDIS) for people with disability

Supporting broader government policies, including productivity and growth

Best practice regulation, along with evidence-based policy and well-targeted programs, support the government to lead and shape Australia's health, disability, and aged care systems. Our regulators are committed to delivering on the Minister's expectations by upholding best practice regulation, including building the necessary data and digital capability. Our approach will place consumers at the centre of regulatory decision-making, ensuring that the safety, wellbeing, and needs of individuals and communities are prioritised alongside productivity, innovation and sustainable growth.

Guided by the RPPPF, we will continue to modernise our approach - embracing digital innovation, streamlining processes, and reducing unnecessary regulatory

burden. Our regulators will ensure regulation remains fit-for-purpose, proportionate and responsive to emerging challenges and opportunities, thereby supporting public value and economic resilience.

The regulatory landscape for Health, Disability and Ageing is complex. Regulators administer legislation that impacts thousands of professionals and organisations, with the aim of improving outcomes and safeguarding the safety and wellbeing of all Australians. We will promote education and a proportionate approach to compliance to modify practice and reduce the risk of harms. We will monitor and adapt to technological, industry, and community changes, updating policies and procedures as needed. In accordance with legislative requirements and the Minister's expectations, we will exercise powers in good faith and to the best of our ability.

Commitment to align with the RMG-128 and RPPPF

Consistent with principles of regulatory stewardship, regulation should protect community health and safety while remaining efficient to administer and comply with legislative requirements. This involves a whole-of-system approach, proactive collaboration, and ongoing review and maintenance of regulatory systems. We will embed best practice principles, regularly evaluate systems, and share expertise with other Commonwealth regulators to drive improved performance. Further detail on how our regulators will do so is set out below.

1. Regulatory oversight of therapeutic goods

The Therapeutic Goods Administration (TGA) will maintain a proportionate, risk-based regulatory framework for therapeutic goods, balancing timely access to products with safety, quality, and efficacy.

The TGA will continue to apply a risk-based approach to post-market surveillance. Regulatory effort will be focused towards therapeutic goods that pose higher risk, strengthen consumer confidence and leverage post-market intelligence from comparable overseas regulators.

The data and digital capabilities of the TGA will continue to be strengthened. This will make business transactions easier for industry, streamline regulatory processes, support evidence-based reforms, and improve productivity through the use of Artificial Intelligence (AI).

- The TGA will continue to consult stakeholders in the development of guidance, technical documents and proposed business improvements and regulatory policy changes. Stakeholders include international counterparts, industry associations, state and territory health departments, health professional bodies, research and academic authorities, and patient and consumer advocacy groups.
- The TGA will collaborate with domestic and international regulators, sponsors, manufacturers, and academics to ensure regulatory frameworks remain fit-for-purpose and responsive to emerging technologies. Participation in international forums will include the International Coalition of Medicines Regulatory Authorities, Access Consortium, International Medical Device Regulators Forum, Medical Device Single Audit Program, Pharmaceutical Inspection

Convention/Cooperation Scheme, and International Pharmaceutical Regulators Program.

- The TGA will continue its strategic focus on international engagement to harmonise regulation and facilitate global information sharing and cooperation.
    - Australia holds a leadership role in shaping global regulatory priorities, strengthening collaboration, and coordinating responses to emerging risks in medicines regulation. The election of the Health Products Regulation Group (HPRG) Deputy Secretary as Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) has strengthened this role.
    - Having achieved World Health Organization (WHO) Listed Authority status, the TGA will continue to work with Access Consortium partners to improve work-sharing and reliance activities.
    - Support will continue for regional regulatory strengthening through initiatives funded by the Department of Foreign Affairs and Trade, including the Regulatory Strengthening Program and the Pacific Medicines Testing Program.
- The TGA will continue to consider approvals from comparable overseas regulators. This will support inclusions in the Australian Register for Therapeutic Goods (ARTG), streamline authorisation processes, advance international harmonisation and bring products to market sooner.
- TGA Learn will continue as a dedicated education service for enterprises, researchers, start-ups and others unfamiliar with therapeutic goods regulation. It will provide self-paced online modules, structured online events, targeted in-person sessions and strategic partnerships. The TGA also collaborates with the Department of Industry, Science and Resources to educate Australian MedTech start-ups, helping them bring their products to market faster.
- The TGA will refine its framework for regulation of medical devices to ensure it remains fit-for-purpose for emerging technologies, including AI models and systems. This work aligns with the National AI plan, emerging standards and guidelines, thereby ensuring Australians have safe, innovative and novel device technologies.
- Compliance, education, and enforcement activities will be intelligence-led and targeted, effectively deterring non-compliance and supporting a commitment to regulatory stewardship and public health protection.

2. Supporting access to subsidised hearing services

- We will engage suppliers of assistive hearing technology and hearing service providers to deliver subsidised hearing support to eligible people under the Hearing Services Program.
- This will be achieved through administration of the *Hearing Services Administration Act 1997*, the Hearing Services Program (Voucher) Instrument 2019, the *Hearing Services Act 1991* and the Australian Hearing Services (Declared Hearing Services) Determination 2025.
- The program supports small business and new market entrants, as any business that can meet the program's requirements can deliver services under the program. The program's requirements, claimable services, and the provider

contract template are published on the department's website, and new applications from providers will continue to be accepted year-round.

- This transparency, easy access to program information and onboarding process will ensure all hearing service providers have equal opportunity to participate.
- Consistent with the Government's regulatory reform agenda, we will simplify the program's current Schedule of Service Items and Fees. This simplification will reduce complexity and administrative burden to providers operating across thousands of delivery sites nationally. In turn, this will lead to a reduction in the likelihood and prevalence of invalid claims.
- A new online portal for providers will be developed to allow program claims forms to be submitted. The portal will support increased efficiency and productivity through its improved functionality.
- These new regulatory approaches will be implemented by 2027 and will allow providers to spend more time delivering hearing services to program clients. Providers will spend less time cross-referencing service claiming rules or engaging with the department due to instances of unintentional non-compliance.

3. Supporting access to pharmaceutical benefits

We will regularly review pharmacy approvals and related policies to simplify processes, reduce regulatory burden, and improve accountability.

We will continue implementing legislation amended in September 2025 which changed how applicant pharmacists seek ministerial discretion to approve a pharmacy for supplying pharmaceutical benefits. The new single-stage, four- month process will shorten waiting times for applicants and remove unnecessary complexity.

Annual reviews of cost recovery arrangements will be undertaken, leveraging digital tools for transparency and efficiency.

- The regulation of pharmacies to supply pharmaceutical benefits will remain appropriate to the current health environment and continue to provide reasonable patient access to medicines.
- Benefits Integrity Division will apply targeted data analysis and intelligence collection to investigate concerns. This will identify providers whose registration, approval, or claiming patterns raise compliance concerns. The results of these detection techniques will continue to be validated through human analysis, including review by health professionals, compliance officers and health and data experts. We will engage with our stakeholders to understand the nature of the concerns and environmental factors that might be relevant to our compliance activities.
- Benefits Integrity Division will engage with stakeholders, including peak bodies and colleges, to ensure compliance activities are commensurate with identified risk and cases are treated appropriately. An educational approach to compliance activities will be applied to ensure consistent and long-term behavioural change, leading to correct claiming of Medicare items. Prior to any legislative change to the approval to supply pharmaceutical benefits, pharmacy industry peak bodies, leading banner groups and pharmacy agents will be engaged. This engagement

will assess the impact of proposed changes on pharmacy businesses and seek suggestions for other changes for consideration.

4. **Supporting the integrity of health benefit claims**
   - We will apply a risk-based, data-driven compliance approach to safeguard public health funding, leveraging digital technology to detect and address fraud and inappropriate practice.
   - Compliance activities will be proportionate to risk and resource requirements, minimizing unnecessary burden.
   - We will identify opportunities to improve regulatory frameworks, by:
     - reducing waste and avoiding non-compliance through shaping effective regulation, design (program and policy) and assisting practitioners to understand their obligations;
     - leveraging intelligence, data, technology and capability to disrupt, prevent and identify risks;
     - initiating effective investigations into non-compliance and fraud;
     - pursuing inappropriate practise and billing anywhere and by anyone; and
     - effective recovery and litigation.
5. **Regulatory oversight of private health insurance and private hospitals**
   - We will engage with the sector and consumers to identify opportunities for regulatory streamlining and innovation, supporting service delivery and reducing administrative costs.
6. **Regulating vaping goods (including e-cigarettes)**
   - We will maintain proportionate, risk-based regulation of therapeutic vaping products, balancing public health protections with access to lawful therapeutic access, where clinically appropriate.
   - We will strengthen regulatory safeguards to deter and disrupt the unlawful importation, supply, possession and advertising of vaping products. At the same time, we will support essential regulatory functions that ensure therapeutic vaping goods remain available through pharmacies.
7. **Regulatory oversight of tobacco products**
   - We will uphold robust and risk-proportionate regulation of elements of the tobacco industry, including tobacco products, advertising, sponsorship and accessories. Through the administration of new tobacco legislation, we will adopt a more proactive regulatory role, enabled by a corresponding uplift in compliance and enforcement capacity.
   - We will identify opportunities to enhance regulatory connections and support a robust, coordinated and streamlined framework of tobacco-related regulatory activities across Australia. This will include the TGA through its regulation of vaping goods, other relevant Commonwealth regulators, and states and territories.
8. **Regulatory oversight of supports and services, outside of the National Disability Insurance Scheme (NDIS) for people with disability**
   - We will regulate supports and services under the *Disability Services and Inclusion Act 2023* (DSI Act), working collaboratively with the Department of Social Services (DSS) to ensure consistency and proportionality.

- We will continue to identify opportunities to improve regulatory frameworks and processes under the DSI Act, in collaboration with DSS.
- We will continue to review regulatory functions under the DSI Act to ensure compliance requirements are proportionate to risk and resource requirements. This will include minimising unnecessary burdens on service providers, while ensuring the safety and quality of disability services being delivered, for example through regulated activity assessments.
- Compliance requirements will be transparent for service providers.

Relationship with Minister and Portfolio

Regulators recognise their responsibility in supporting the Minister, the broader government, and the portfolio in carrying out their regulatory duties. We will maintain and strengthen this constructive relationship through regular, timely, and transparent engagement with the Minister. This will ensure that policy and regulatory developments are communicated consistently. Additionally, we will work closely with the portfolio to offer agencies guidance and assistance in fulfilling their regulatory responsibilities.

The SOI along with the SOE will be incorporated into our performance reporting, including the corporate plan and annual reporting processes. This will include the development of Key Performance Indicators and service standards.

We will engage with the Minister and stakeholders to collaborate, ensuring safer, higher quality services and better outcomes for Australians.

Blair Comley PSM
Secretary
Department of Health, Disability and Ageing

5 March 2026