



Australian Government

Department of Health and Aged Care

Statement of Intent

This Statement of Intent (SOI) responds to the Statement of Expectations (SOE) provided by the Minister for Health and Aged Care to me on 21 June 2023, concerning certain departmental regulatory functions under the *Regulator Performance (RMG 128)* (“*The Guide*”). It sets out my intentions regarding how our regulators and regulatory functions will deliver on those expectations to achieve regulatory objectives, carry out regulatory functions, and exercise powers.

Introduction

The Health and Aged Care portfolio has 11 participating regulators or regulatory functions, of which three are portfolio regulators who have their own SOIs – Professional Services Review, the Aged Care Quality and Safety Commission, and, Sport Integrity Australia. Two of the departmental regulators which involve statutory appointments, the Gene Technology Regulator and the Executive Director of the Australian Industrial Chemicals Introduction Scheme, also have their own SOIs.

This SOI implements the intents of the Regulator Performance Guide for the remaining six departmental regulatory functions:

- regulatory oversight of therapeutic goods
- regulatory oversight of controlled drugs
- supporting access to high quality hearing services
- supporting access to pharmaceutical benefits
- supporting the integrity of health benefit claims
- regulatory oversight of private health insurance and private hospitals

This SOI outlines our approach to regulatory stewardship, integrating the principles of regulator best practice and stakeholder relationship management, the Government’s policy priorities, and innovation and regulatory change. It was prepared following consultation with each of the participating regulators or regulatory functions.

Overview

The regulatory environment in the health and aged care sector is complex and broad ranging. The Commonwealth, through the Department and its portfolio agencies, has significant responsibility for health services, including primary care and health insurance. Our regulators play a vital role administering legislation that covers thousands of professionals, organisations and businesses that support the health and wellbeing of Australians.

Through our regulation, we aim to protect the health, safety and well-being of all Australians, by identifying risks to human health and the environment, and managing those risks to prevent harm, through education and effective and proportionate compliance activities.

A number of significant events have tested our regulatory frameworks, including the Royal Commission into Aged Care Quality and Safety and the Productivity Commission report into mental health. The lessons learnt will be applied to our regulatory frameworks, including the continuation of more streamlined regulatory processes where regulators work within a more responsive framework for decision-making, without compromise to public health and safety.

In accordance with the requirements of the applicable legislation underpinning each function and consistent with the expectations outlined by the Minister, our regulators will continue to exercise their regulatory functions and powers in good faith and to the best of their ability.

Regulatory stewardship

Stewardship covers the range of functions that our regulators undertake to help ensure regulation is effective at meeting its objectives to protect the health and safety of the community while making regulation work as efficiently as possible. Effective regulatory stewardship will involve the adoption of a whole-of-system view of regulation, and taking a proactive, collaborative approach to the care of the regulatory systems which my department oversees.

Our regulators will seek to embed the principles set out in *The Guide* and will:

- view our regulatory systems as assets that need to be regularly reviewed and maintained to deliver effectively over time
- take a whole-of-system, life-cycle view of regulation
- adopt a proactive, collaborative approach to the monitoring and evaluation of our regulatory systems to ensure they remain fit-for-purpose

To achieve this, we will continue to engage with other Commonwealth regulators and portfolios and share our regulatory expertise to help drive improved regulator performance at a whole-of-system level.

Principles of regulator best practice

Consistent with the expectations of the Minister, our regulators will implement their functions in ways which support the three main principles of the *The Guide*:

1. Continuous improvement and building trust

Our regulators will:

- adopt a whole-of-system perspective, continuously improving their performance, capability and culture, to build trust and confidence in Australia's regulatory settings
- use quantitative and qualitative analysis as important tools for assessing and reporting on performance. Our delivery against performance measures will be

reported in documents such as the Corporate Plan and Annual Report, thereby supporting continuous improvement

- promote a work culture that builds public confidence in the Department's work and promotes trust in government decision-making

Our regulators will continue to maintain a function dedicated to providing advice, assistance and training to Health and Aged Care portfolio regulators and policy areas on best practice policy and regulation. This includes the development of Best Practice Guides on various aspects of regulatory policy, such as how to draft Impact Analysis documentation, managing stakeholder engagement, adopting risk-based approaches and managing non-compliance.

Our regulators will continue to provide opportunities for continual improvement and ensure regulator practices are fit-for-purpose. This includes maintaining and regularly reviewing Memoranda of Understanding with relevant practitioner professional bodies for the Hearing Services Program (HSP), and regular engagement with representative bodies of business-related stakeholders, including HSP contracted service providers and device suppliers.

We will ensure the regulation of pharmacies to supply pharmaceutical benefits remains appropriate to the current health environment and continues to provide reasonable patient access to medicines.

We will identify opportunities to improve its regulatory frameworks, such as the Benefits Integrity Division's (BID) Medicare compliance program, which prepares monthly comprehensive performance dashboard reviews of the outcomes of compliance activities and undertakes internal quality audits.

2. Risk-based and data-driven

Our regulators will:

- seek opportunities to remove duplication and streamline processes in order to improve efficiency and lift productivity, including international harmonisation and alignment with international regulators, as appropriate
- maintain essential safeguards, using data and digital technology to manage risks proportionately to minimise regulatory burden and to support those it regulates to comply with and enhance their understanding of the requirements of each regulatory function the Department administers
- actively understand, engage with and effectively mitigate strategic risks in order to successfully manage its regulatory functions
- use data sources that meet relevant data assurance standards for assessing and reporting on the quality of statistical information

Our regulators will continue to maintain and review compliance and enforcement policies that outline regulatory approaches to identify and manage risk. We will seek to make complying with regulation as efficient as possible while increasing voluntary compliance.

The Therapeutic Goods Administration (TGA) Digital Transformation initiative will continue to allow industry to securely interact with Government to apply for, track,

pay and manage listings for regulated goods electronically, rather than manually or via hardcopy submissions, and, deliver contemporary digital capability over time that makes it easier for industry to complete business transactions with the TGA and the Office of Drug Control (ODC).

Additionally, BID will continue to apply targeted data analysis and intelligence collection to investigate concerns and identify providers whose registration, approval, or claiming patterns raise compliance concerns. The results of these detection techniques are validated through human analysis, including review by health professionals, compliance officers and health and data experts. BID engages with our stakeholders to understand the nature of the concerns and environmental factors that might be relevant to our compliance activities.

The HSP has comprehensive data analytics, in conjunction with other internal/external risk signals, to support risk-based prioritisation of compliance activities, particularly where there are shared risks. This is underpinned by its transparent Compliance Monitoring and Support Framework.

3. Collaboration and engagement

To ensure our regulators are transparent and responsive, implementing regulations in a modern and collaborative way, and being open, transparent and consistent when engaging with stakeholders including industry, government and the broader community, our regulators will:

- seek opportunities to engage and consult genuinely with stakeholders
- be receptive to feedback and diverse stakeholder views
- be transparent in their decision-making processes
- provide up-to-date, clear and accessible guidance and information to assist regulated entities with compliance

Our regulators will continue to engage with stakeholders. For example, the ODC will continue consultation with industry and stakeholders, including state and territory regulators and law enforcement agencies, in relation to regulatory frameworks and practices such as the Medicinal Cannabis Scheme. The ODC also attends a number of industry conferences each year to provide stakeholders with updates and opportunities to raise issues.

BID will continue to regularly engage with key internal and external stakeholders, including peak bodies and colleges, to ensure compliance activities are commensurate with identified risk and the appropriate treatment of cases is applied. Wherever appropriate, BID will apply an educational approach to compliance activities with the goal of ensuring consistent and long-term behavioural change, leading to correct claiming of Medicare items. Prior to making any changes to the legislation which regulates approval to supply pharmaceutical benefits, pharmacy industry peak bodies, leading banner groups and pharmacy agents will be engaged to determine the impact of proposed changes on pharmacy businesses, and to seek suggestions for other changes for consideration.

The Hearing Services and Chronic Conditions Branch meets with audiological Practitioner Professional Bodies on a quarterly basis and has legislation which

supports sharing of information to support and ensure HSP practitioner compliance with program requirements. Additionally, the program engages proactively with providers to seek feedback and support continuous improvement for program assurance and compliance.

The TGA will continue to consult with internal and external stakeholders in the development of guidance, technical documents and proposed business improvements or regulatory policy changes. These include peak therapeutic goods industry associations, state and territory health departments, professional guilds and patient/consumer advocacy groups. An example affecting industry, patients, consumers, state and territory governments and healthcare practitioners is the ongoing consultation on reforms to the therapeutic goods recall processes.

The TGA also continues to engage participants in a number of international forums including the International Medical Device Regulators Forum, the Pharmaceutical Inspection Convention/Cooperation Scheme, the International Pharmaceutical Regulators Programme and the Access Consortium, with the aim of harmonising regulation and facilitating global information sharing and cooperation.

Our regulators acknowledge the importance of the principles of regulator best practice in ensuring compliance with national standards of accreditation and maintaining constructive stakeholder relationships in the regulatory environment. We will embed the principles of regulator best practice as outlined in *The Guide* into the operation of our regulatory functions and apply performance reporting to assess how well we have done.

Relationship with our regulated entities

Our regulators represent a broad cross-section of the Australian community. In our regulatory capacity, we will be consistent, responsive, transparent, and act proportionately and appropriately when dealing with our regulated entities. We will:

- educate our regulated entities about the purpose of regulation, their obligations and how to comply, including what to expect (if found to be non-compliant)
- assess applications in a timely manner
- assess and set conditions guided by a risk-based approach
- deter non-compliance by having easy-to-follow processes
- detect compliance risks through ongoing monitoring and evaluation
- apply regulatory interventions using a range of actions proportionate to the prevailing risk
- evaluate our regulations to ensure they remain fit-for-purpose and do not impose unnecessary burdens

To improve the delivery of our regulatory functions and to build and maintain trust, accountability and integrity, our regulators will continue to effectively engage with regulated entities through initiatives including:

- TGA Learn, a dedicated service that the TGA offers to help enterprises, researchers, start-ups and those unfamiliar with therapeutic goods regulation understand their regulatory and legislative obligations. The

service delivers self-paced online education, structured online learning events, targeted in-person events and strategic partnerships

- the final report of the *Independent Review of Medicare Integrity and Compliance*, published in March 2023, includes 23 recommendations across governance and structure, operational processes, modernising technology and strengthening legislation. BID will work alongside health practitioners, patients and peak bodies to develop a comprehensive response
- the AskMBS email service within BID which responds to enquiries from providers of services listed on the Medicare Benefits Schedule (MBS) seeking advice on the interpretation of MBS items (including those for dental, pathology and diagnostic imaging), explanatory notes and associated legislation. This advice will continue to assist health professionals, practice managers and others to understand and comply with MBS billing requirements

The Government's policy priorities and objectives

Our regulators are committed to maintaining well-designed and fit-for-purpose regulations for therapeutic goods, controlled drugs, scheduling of medicines and poisons, supporting access to high quality hearing services, supporting access to pharmaceutical benefits, supporting the integrity of health benefit claims, and private health insurance.

We will contribute to the government's regulatory reform agenda by:

- acting in accordance with principles of regulator best practice in its decision-making, policies, processes and communication practices
- applying *The Guide* to our regulatory functions to assess regulator performance and engagement with stakeholders
- continuing to implement the principles set out in the *Health Regulatory Performance Framework*
- incorporating regulator performance reporting into the Department's reporting processes as provided in *The Guide*, in-line with the *Public Governance, Performance and Accountability Act 2013* and the *Public Governance, Performance and Accountability Rule 2014*
- considering the application of cost recovery arrangements, where appropriate

Innovation and regulatory change

Our regulators will continue to monitor the environment they operate in to ensure that regulatory approaches keep pace with changes in technology, industry practices, international regulation, and community expectations. We will also regularly review and, where necessary, adjust policies, protocols and operating procedures to ensure we can respond to the changing social, technological and international regulatory environment, as well as the commercial context, in which our regulators operate.

As an example, the TGA will continue to work closely with international regulators and other Australian Government agencies to improve regulatory systems, share information, improve supply chain resilience, and develop strategies to improve regulatory reliance and harmonisation. For example, the

Comparable Overseas Regulator (COR) report-based pathway allows the TGA to use assessment reports from comparable overseas regulators when assessing applications for market authorisation of therapeutic products in Australia.

The TGA will also continue to deliver the Action Plan for Medical Devices. This will improve how new devices get on the market in Australia, strengthen monitoring and follow up of devices already in use, and, provide more information to patients about the devices they use.

Relationship with Minister and portfolio

Our regulators acknowledge their role in supporting the Minister, the government more broadly and the portfolio in performing their regulatory functions. We will continue to contribute to this productive relationship through consistent, timely and transparent engagement with the Minister, to ensure that developments in policy and regulation are regularly informed. We will also engage with the portfolio to provide agencies with guidance and support in performing their regulatory functions.

Our regulators will integrate the SOE and SOI into performance reporting as part of its corporate plan and annual report processes.

Dr Brendan Murphy
Secretary
Department of Health and Aged Care
21 July 2023