



Australian Government

Department of Health
and Aged Care

Administration of Commonwealth Regulations

Submission from the Department of Health and Aged Care
to the Joint Committee of Public Accounts and Audit

22 August 2024



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Introduction

The Department of Health and Aged Care (the department) welcomes the opportunity to make a submission to the Joint Committee of Public Accounts and Audit's inquiry into the *Administration of Commonwealth Regulation*.

Term(s) of reference: The Committee will examine how Commonwealth entities assess compliance risk, inform compliance and enforcement strategies, and identify and address incidences of non-compliance with Commonwealth rules and regulations. Performance and evaluation frameworks for compliance with Commonwealth regulations will also be assessed.

The department will address the above terms of reference through the following areas:

- Therapeutic Goods Administration
- Residential aged care mandatory minimum staffing standards
- Tobacco product requirements as examined in Auditor-General Report No.5 of 2023–24.

Therapeutic Goods Administration

Background

The Therapeutic Goods Administration (TGA) sits in the department's Health Product Regulations Group (HPRG). The TGA is the Australian Government's regulatory authority responsible for evaluating, assessing and monitoring therapeutic goods under the *Therapeutic Goods Act 1989*¹ (the TGA Act). The TGA's compliance activities aim to deter and disrupt non-compliant import, export, manufacture, supply and advertising of therapeutic goods in Australia. This work is supported by intelligence-led and risk-based compliance policy and education activities.

Establish risk-based compliance strategies

Regulatory compliance activities are aligned to the TGA's Regulatory Compliance Framework² and its five key principles. The department establishes priorities³ for compliance activities under the TGA Act which are risk-based, aligned with strategic objectives and informed by proactive and responsive monitoring strategies. The department currently renews these annually however is soon moving to a bi-yearly renewal process. This will ensure priorities reflect the complex and changing landscape, including regulatory changes, to maximise the efficiency of compliance activities.

¹ <https://www.legislation.gov.au/Series/C2004A03952>

² <https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/compliance-management>

³ <https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/compliance-management/import-advertising-and-supply-compliance-priorities-2023-24>



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Regulatory changes are often related to identified risks to the public. The department's systems aim to be responsive to emerging regulatory risks, such as the recent nicotine vaping reforms⁴. In response, the Australian Government provided funding to the department and the Australian Border Force to conduct compliance and enforcement operations. These operations have commenced, under the National Vaping Enforcement Framework⁵, which is overseen by a multi-agency National Vaping Working Group.

Identify and address incidences of non-compliance

The department receives tip-offs and referrals for potential non-compliance with the TGA Act from the public, other agencies, regulators and law enforcement. Reports are triaged for action based on a risk-based *Priority Scoring Matrix* for investigation. An additional set of priority scoring criteria is applied to cases requiring investigation to determine the relative priority. This approach is flexible to changing regulatory needs and compliance priorities.

The TGA Act and supporting regulations provide investigative powers and enforcement actions such as infringement notices and enforceable undertakings. These measures may apply where a person breaches a requirement of the TGA Act or engages in behaviour that poses a risk to public health and safety. The department also uses non-statutory compliance responses, such as warning letters. The department's application of enforcement action is evidence-based and adjusts to the nature and seriousness of the alleged non-compliance, and the potential risk to public health and safety.

Relevant 2023-24 financial year compliance enforcement actions for non-compliance with the TGA Act are outlined below.

- Issued nearly 8,000 warning letters across close to 14,000 cases for the unlawful import, support and advertising of therapeutic goods
- Seized over 8,000,000 goods for unlawful import
- Sent over 4,800 content removal requests for unlawful advertising of therapeutic goods on digital platforms
- Issued 190 Infringement Notices at a value of over \$2,500,000
- Finalised over 2,500 nicotine related investigations.

⁴ <https://www.tga.gov.au/products/unapproved-therapeutic-goods/vaping-hub/changes-regulation-vapes#:~:text=Changes%20from%201%20July%202024&text=The%20domestic%20manufacture%2C%20commercial%20possession,nicotine%20or%20other%20controlled%20substances,and https://www.tga.gov.au/news/blog/nicotine-vaping-laws-are-changing>

⁵ [Vapes: compliance and enforcement | Therapeutic Goods Administration \(TGA\)](#)



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The department uses digital platforms and advertising where appropriate to complement regular compliance activities. The department monitors online content for unlawful advertising and/or supply of therapeutic goods via web platforms. When identified on a risk-proportionate basis, the department can make disruption requests under Section 313(3) of the *Telecommunications Act 1997*⁶, asking internet service providers (ISPs) to block specific websites containing unlawful information. Since late 2023, the department has requested over 75 domains be blocked.

Performance and evaluation frameworks

The department is currently reviewing its external performance reporting in response to the ANAO 2023/24 performance statements audit. This response will also reflect the related recommendation in the Auditor-General Report No.3 2023–24. To support this, the TGA is examining how current data is captured and reported, and ways to improve this to enhance insights and measure performance.

Residential aged care mandatory minimum staffing standards

Background

The department manages the legislative and regulatory framework and supporting funding arrangements for Commonwealth-funded aged care services such as residential aged care. Residential aged care is subsidised by the Commonwealth with payments made directly to approved providers that must meet specified standards of care. In May 2021, the Australian Government accepted Recommendation 86 from the Royal Commission into Aged Care Quality and Safety to introduce mandatory minimum staffing standards, consisting of a:

- minimum standard amount of direct care time an average resident receives each day (Care Minutes)
- requirement that a registered nurse (RN) be onsite and on duty for a prescribed number of hours each day (24/7 RN).

The standard of care is regulated by the Aged Care Quality and Safety Commission (ACQSC) including compliance with the Care Minute and 24/7 RN responsibilities.

Establish risk-based compliance strategies

The department's role with respect to compliance with mandatory minimum staffing standards in residential aged care is limited to assuring the accuracy of reporting by providers and managing exemptions to the 24/7 RN responsibility.

⁶ s313(3) requires that carriers and carriage service providers give officers and authorities of the Commonwealth, states and territories such help as is reasonably necessary to enforce the criminal law and laws imposing pecuniary penalties - [TELECOMMUNICATIONS ACT 1997 - SECT 313 Obligations of carriers and carriage service providers \(austlii.edu.au\)](#)



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The department's strategy with respect to assuring the accuracy of reporting is to identify the providers with the highest risk of reporting misstatements based on the impact and likelihood of misstatement. This assessment is informed by historical patterns and the department's robust information systems including information gathered from the ACQSC, Star Ratings and MyAgedCare.

The Secretary delegates grants exemptions to the RN 24/7 in line with the criteria set out in Section 15S of the *Quality of Care Principles*. These criteria require the delegate to be satisfied that the provider has taken reasonable steps to ensure that the clinical care needs of the care recipients in the facility will be met while the exemption is in force. The delegate satisfies themselves with reference to a risk-based assessment performed by the department, using information provided by the ACQSC.

The RN 24/7 responsibility came into force on 1 July 2023. The Auditor-General Report No.8 of 2023-24 found there were delays in assessing and applying exemptions in 2022-23, with no applications approved prior to 1 July 2023. The department has streamlined the process for assessing exemptions for 2023-24, with all exemption applications received for 2024-25 processed before the end of June 2024.

Identify and address incidences of non-compliance

The department applies a data driven risk-based prioritisation approach to identifying misreporting against the Care Minute and 24/7 RN responsibilities by specific aged care providers. The Assessment Site Identification Tool takes a risk-based approach to prioritising services for reporting assessments. This considers factors such as the reported cost of the care minutes and outlier performance against the responsibilities.

Once selected, data-analytics is used to identify the areas of highest risk to inform the assessment. These compare the cost of the care minutes reported against those reported by other services and to identify significant, unexpected changes in performance. When misreporting is identified as part of a reporting assessment, the department considers the below factors.

- the extent and nature of the misreporting identified
- whether the misreporting is deliberate
- if practices are repeated across other services held by the provider
- whether the misreporting impacts the payment of the 24/7 RN supplement.

Since September 2023, the program has completed 80 reporting assessments, with 148 in-progress. The in-progress or complete assessments cover 198 of the 754 approved providers of residential aged care in Australia. These approved providers own 1,782 of the 2,617 residential aged care services in Australia, providing indirect coverage over half of the sector.



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Where misreporting is deliberate, or for services which repeatedly misreport, the department may refer the matter to the ACQSC and undertake an investigation into specific breaches of the Criminal Code.⁷ The department prioritises an educative response when misreporting is not deliberate. This includes correcting the reporting to the department and updating the information available about the service on MyAgedCare. The department is also communicating with the sector about common errors and developing tools to support providers in reporting accurately.

Performance and evaluation frameworks

The department is currently reviewing its external performance reporting in response to the ANAO 2023/24 performance statements audit. This is anticipated to include performance reporting for residential aged care.

The department has developed an evaluation framework to review the implementation of the Care Minutes and 24/7 RN responsibilities and underlying policy. In addition, the department is establishing a quality assurance function to ensure reporting assessments are compliant with procedures.

Tobacco product requirements

Background

The department is responsible for administering the *Public Health (Tobacco and Other Products) Act 2023* (Tobacco Act) which commenced on 1 April 2024. The Tobacco Act consolidates the *Tobacco Plain Packaging Act 2011* (TPP Act), the *Tobacco Advertising Prohibition Act 1992* (TAP Act), and other tobacco related instruments into one piece of legislation with associated regulations.

The ‘tobacco product requirements’ of the Tobacco Act require all tobacco products in Australia to be sold in plain packaging and feature graphic health warnings. Monitoring and enforcement of plain packaging and other tobacco product requirements is an essential component of Australia's comprehensive approach to tobacco control. Routine education and inspection of retailers of tobacco products is performed on behalf of the department by the Department of Industry, Science and Resources (DISR) through the National Measurement Institute (NMI) who administer Australia’s trade measurement laws.

The role of NMI in conducting tobacco plain packaging inspection activities is governed by a Memorandum of Understanding (MoU) between the department and DISR. Under the MoU, compliance and enforcement activities undertaken by NMI may include inspections of manufacturers/retailers or suppliers of tobacco products. Routine activities also include information visits to tobacco suppliers and retailers.

⁷ Relevant divisions of the *Criminal Code Act 1995* may include divisions 134, 135 and 137.



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Establish risk-based compliance strategies

The department's Tobacco Control Enforcement Policy⁸ guides decisions and actions in enforcing the Tobacco Act. In enforcing the provisions of the relevant legislation, the department's primary aims are to:

- ensure the highest level of compliance with the relevant legislation
- educate and inform tobacco suppliers of their obligations
- deter future non-compliance
- encourage reporting of non-compliance (including self-reporting of an error)

Identify and address incidences of non-compliance

The department utilises complaints and referrals, and inspection and information visits performed by NMI to identify non-compliance with the tobacco packaging requirements. These activities ensure the greatest possible exposure to compliance activities and information from the resources available.

As the Tobacco Act gives effect to public health aims, the department seeks to encourage compliance to ensure consumers receive the full suite of strategies to reduce smoking prevalence and tobacco consumption. A proportionate enforcement measure is selected using risk-based tiering which considers the level of non-compliance. The department addresses non-compliance through the below. Where the department holds suspicion of organised criminal activity occurring, the information is referred to relevant law enforcement authorities.

- issuing warning letters
- issuing infringement notices
- seeking enforceable undertakings or injunctions
- pursuing civil penalties or referral to the Commonwealth Director of Prosecutions.

The 2023-24 financial year compliance enforcement actions for non-compliance related to the TPP Act and the Tobacco Act are outlined below.

- Prior to the date of repeal (1 April 2024) of the *Tobacco Plain Packaging Act 2011*:
 - 233 potential contraventions were investigated
 - 101 warning letters were issued
 - 720 educative information visits of tobacco retail outlets were undertaken by NMI
 - 224 follow up inspection visits of tobacco retail outlets were undertaken by NMI
- From 1 April 2024 until 30 June 2024, 4 investigations into potential contraventions to tobacco product requirements were initiated.

⁸ <https://www.health.gov.au/resources/publications/tobacco-control-enforcement-policy>



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Performance and evaluation frameworks

The department undertakes an annual evaluation performance and impact of the activities relating to tobacco packaging requirements under the MoU with NMI to ensure that resources are allocated in the most efficient and effective manner to identify and address non-compliance. This includes a review of the information and inspection activities undertaken by the NMI.

Summary

The department establishes strategic priorities to guide regulatory compliance activities which are risk based and aligned to strategic objectives. These are reviewed regularly to ensure that emerging risks are reflected. The department is constantly monitoring for emerging risks, once identified compliance activities respond with a shift in priorities and resourcing.

The department's regulatory compliance functions rely on a mixture of tip-offs, referrals and intelligence gathering to identify potential non-compliance. The department takes a risk-proportionate approach to assessing compliance risk which is informed by robust information systems, proactive intelligence gathering and data analytics.

The department applies a range of statutory and non-statutory compliance responses which is determined based on factor such as the type of offence and associated risks. Where possible, the department also uses digital platforms, education and communications to complement regular compliance activities.

The department aims to publicly report on the number and outcomes of core compliance activities to promote transparency and accountability, where material to the Australian Government and public interest.



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Attachment A – Recommendation implementation

A summary of the department’s progress in implementing recommendations from Auditor-General Report No.3 2023–24 and Auditor-General Report No.8 2023–24 is provided below.

Management of Non-Compliance with the Therapeutic Goods Act 1989 for Unapproved Therapeutic Goods

Recommendation: 1 of 6

Due: 31 July 2024

Status: Revising the implementation timeline to align with the department’s response to the ANAO 2023/24 performance statements audit

The Department of Health and Aged Care review its annually reported performance information for its regulation of therapeutic goods to ensure the information is appropriate and covers the significant components of its key activities.

Recommendation: 2 of 6

Due: 31 July 2024

Status: Requesting closure at the upcoming Audit and Risk Committee

The Department of Health and Aged Care:

- a) finalise its investigation procedures for the regulation of therapeutic goods and ensure these procedures align with requirements of the Australian Government Investigations Standard 2022; and*
- b) establish an internal control for the regular review and update of these investigation procedures.*

Recommendation: 3 of 6

Due: 31 January 2024

Status: Closed

The Department of Health and Aged Care:

- a) ensure that investigators maintain a minimum level of investigator qualification, as required by the Australian Government Investigations Standard 2022; and*
- b) keep appropriate records of investigator qualifications.*

Recommendation: 4 of 6

Due: 31 January 2024

Status: Closed

The Department of Health and Aged Care:

- a) establish an internal control to ensure that officials involved in investigations and compliance activities make and manage declarations of interest; and*
- b) keep appropriate records of declarations of interest.*



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Recommendation: 5 of 6

Due: 28 August 2025

Status: Open

The Department of Health and Aged Care establish:

- a) clear complaint handling channels that are accessible and easy to use; and*
- b) a system for end-to-end complaint management and reporting.*

Recommendation: 6 of 6

Due: 31 July 2024

Status: Requesting closure at the upcoming Audit and Risk Committee

The Department of Health and Aged Care develop an Investigations Quality Assurance Policy, as required by the Australian Government Investigations Standard 2022.

Design and Early Implementation of Residential Aged Care Reforms

Recommendation, 1 of 4*

Due: 30 June 2024

Status: Requesting closure at the upcoming Audit and Risk Committee

The Department of Health and Aged Care ensure that Risk Potential Assessment Tools are completed in accordance with Australian Government policy, in particular the requirement to complete a Risk Potential Assessment Tool for new policy proposals with a financial impact of \$30 million, and the requirement to revise a Risk Potential Assessment Tool for approved policy proposals when there is a significant change to one or more risk factors affecting implementation. The Department of Health and Aged Care should promote the use of the Risk Potential Assessment Tool for new policy proposals of less than \$30 million.

Recommendation, 2 of 4*

Due: 30 June 2024

Status: Requesting closure at the upcoming Audit and Risk Committee

The Department of Health and Aged Care establish evaluation plans for mandatory care minutes and 24/7 RN in order to settle on the policy objectives to be assessed, potential data sources, baseline data, data collection mechanisms and specific timeframes. Gaps in information required for an effective evaluation should be identified and rectified as part of implementation.

*Recommendations 3 and 4 were directed to the ACQSC.