Health Legislation Amendment (Improved Medicare Integrity and Other Measures) Bill 2025

Submission from the Department of Health and Aged Care
to the Senate Standing Committee on Community Affairs Legislation

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Contents

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Introduction

The Department of Health and Aged Care (department) welcomes the opportunity to make a submission to the Senate Community Affairs Legislation Committee's Inquiry into the Health Legislation Amendment (Improved Medicare Integrity and Other Measures) Bill 2025 (Bill).

The Bill would amend the following primary legislation in the Health and Aged Care portfolio:

- *Health Insurance Act 1973* (Health Insurance Act);
- *National Health Act 1953* (National Health Act);
- *Human Services (Medicare) Act 1973* (Human Services Medicare Act);
- *Dental Benefits Act 2008* (Dental Benefits Act);
- *Therapeutic Goods Act 1989* (Therapeutic Goods Act);
- *Public Health (Tobacco and Other Products) Act 2023* (Tobacco Act).

Broadly, these amendments would implement several important measures intended to protect the integrity of Medicare, enhance the regulation of therapeutic goods and vaping goods under the Therapeutic Goods Act, and make minor amendments to the Tobacco Act.

This submission outlines the objectives of some of the key integrity and public health measures that would be introduced by this Bill. Further detail on the contents of the Bill and the consultation undertaken in its development is available in the Revised Explanatory Memorandum. The department would like to draw the Committee's attention to the Minister's responses to the Senate Standing Committee for the Scrutiny of Bills (Scrutiny of Bills Committee), dated 18 February and 3 March, relating to a small number of measures contained in the Bill. The Minister's responses to the Scrutiny of Bills Committee are expected to be published shortly.

Overview of Bill

The amendments relating to Medicare integrity are principally intended to:

a) change the usual timeframe for making claims for payment in respect of bulk-billed services from 2 years to 1 year;
b) update and broaden investigative powers to ensure they can be used appropriately across health benefits schemes and in relation to a broader number of offences;
c) improve pharmacy approval processes;
d) improve powers to obtain information about potential non-compliance and readily ascertain amounts that should not have been paid; and

Australian Government
Department of Health and Aged Care

e) remove restrictions on the admission of some information, obtained under the notice to produce powers of the Professional Services Review (PSR), as evidence in certain proceedings.

The Bill would also amend the Therapeutic Goods Act to, among other things:

a) enhance the effectiveness of the Secretary's power to address and alleviate the consequences of critical shortages of therapeutic goods in Australia;
b) enable regulations to be made to prescribe circumstances in which the Secretary must not authorise a medical practitioner, under the Authorised Prescriber Scheme, to supply therapeutic goods that are not included in the Australian Register of Therapeutic Goods;
c) revise several provisions in Part 6-2 that deal with entry to and searches of premises, as well as warrants to undertake such action, to ensure they are better aligned with the model provisions in the *Regulatory Powers (Standard Provisions) Act 2014*; and
d) improve the flexibility and effectiveness of the Secretary's compliance and enforcement powers to remove unlawful and unsafe therapeutic goods and vaping goods from the market.

The Bill would amend the Tobacco Act to, among other things, enable the making of regulations to facilitate smooth phase in and phase out of future series of regulated tobacco product requirements.

Measures relating to Medicare integrity

The department is responsible for protecting the integrity of Australia's health payments system comprising the Medicare Benefits Schedule (MBS), the Pharmaceutical Benefits Scheme (PBS) and the Child Dental Benefits Schedule (CDBS). The ongoing viability of these programs is of the utmost importance to the Commonwealth. In 2023-24, payments for personal benefits including medical services, pharmaceutical services and private health insurance rebates totalled at least $65 billion.

The department and the PSR's compliance activities protect Commonwealth expenditure enabling further investment in Australia's health programs. It is essential that there are robust structures in place to identify and address incorrect payments and non-compliance. Such structures ensure that public resources are directed to necessary health services, and to ensure that health benefits schemes are – and continue to be – sustainable.

The Independent Review of Medicare Integrity and Compliance was undertaken by health economist Dr Pradeep Philip (Philip Review). The Philip Review focussed on the Medicare payment system and specifically on the integrity of claims for payment made by health practitioners. The Philip Review made a range of recommendations about how the integrity of Medicare programs could be strengthened, and how compliance processes could be

Australian Government
Department of Health and Aged Care

improved. The measures in the Bill respond to some of the recommendations of the Philip Review.

Timeframes for making bulk billed claims

The Bill proposes to change the usual maximum timeframe during which claims relating to bulk-billed Medicare and dental services may be made. The maximum timeframe would change from 2 years to 1 year.

Allowing a longer period of time between a service and a claim can increase the likelihood of incorrect payments and possible fraud, due to reduced visibility of services. As a result, this change would improve payment integrity and reduce the number of incorrect and fraudulently made claims which is consistent with the recommendations of the Philip Review. The Minister (for Medicare claims) and the Chief Executive Medicare (for dental claims) would continue to have discretion to allow claims to be made after 1 year in appropriate circumstances. This is likely to have minimal impact on patients and practitioners as most claims are already made within 1 year, and there would be capacity to accept genuine claims after this on a discretionary basis to ensure patients and practitioners are not disadvantaged.

Investigative powers

The investigative powers in Part IID of the *Human Services (Medicare) Act 1973* currently apply inconsistently due to the definition of 'relevant offence' in section 3A of that Act. As a result, authorised officers are unable to undertake investigations in respect of numerous offences, including offences under the *Criminal Code Act 1995* (Criminal Code) and offences relating to PBS fraud. For example, current provisions do not enable notices to produce documents to be given in relation to some offences relating to the supply of pharmaceutical benefits. This impacts the responsiveness and public burden required to investigate and address potential fraud matters.

The Bill would amend the definition of 'relevant offence' to enable a consistent suite of powers for the investigation of Medicare fraud offences by authorised officers. The changes would enable investigations in respect of more criminal offences – including offences in the Criminal Code such as money laundering, forgery and identity fraud offences.

The changes would improve the use of the investigative powers, addressing gaps and inconsistencies in the current application of the provisions in accordance with the recommendations in the Philip Review. This would result in greater scope to investigate and efficiently respond to potential non-compliance and fraud.

Australian Government
Department of Health and Aged Care

Pharmacy approval processes

The National Health Act provides that the Secretary of the department may, upon application by a pharmacist, approve a pharmacist to supply pharmaceutical benefits from particular premises.

If an application does not meet certain requirements, the Minister has a discretionary power to substitute the Secretary's rejection decision and instead approve the application. The process for the exercise of this discretionary power is set out in legislation.

The proposed changes would replace the current two stage process with a single stage process. This would reduce the standard timeframes from approximately six months to four months.

If the Minister decides not to exercise discretion to approve a request, the changes would prevent the applicant from making another request to the Minister for the same premises, within 12 months. This would reduce administrative burden on public resources caused by repeat applications without merit.

The Bill would also enable the Minister to delegate the power to approve the relevant application form for a Ministerial request, and to increase the membership term for the Australian Community Pharmacy Authority from 2 years to 3 years.

Collectively, these changes would streamline the pharmacist approval process and consequently reduce administrative burden on public resources.

Administrative inquiries and recoveries

The findings from the Philip Review highlighted the need for a more flexible compliance framework to provide more options for gathering information and identifying and appropriately responding to non-compliance. Some existing restrictions and limitations are impacting the ability of the department to ensure incorrectly paid amounts are appropriately responded to. For example, current recovery mechanisms generally rely on outdated claiming processes and requests for hard copy documents.

The Bill would broaden powers to obtain information about Medicare services and increase capability to identify potential non-compliance with the Health Insurance Act. The proposals would also enable the recovery of payments that did not meet relevant requirements.

The changes would enable decision-makers to seek information about matters relevant to the administration of the Health Insurance Act and Medicare payments. This would ensure decision-makers have sufficient information to consider appropriate action to address non-compliance. For example, debt recovery action or (where warranted) criminal and civil proceedings. Further, amendments are proposed to broaden the circumstances in which

amounts may be recovered if a person was not entitled to receive a Medicare payment, or if the legislative requirements for a payment were not met.

These measures would improve powers to address incorrect claiming and recover monies and directly respond to the recommendations in the Philip Review.

Removing some restrictions on admission of evidence

The Philip Review also referred to the need to support the accessibility, quality, and safety of health services. The Bill would remove restrictions on the admission of information obtained under the PSR's notice to produce powers as evidence in some proceedings. This would include proceedings for the purposes of whether practitioners are able to be registered to practice under the Health Practitioner Regulation National Law.

Restrictions on the admission of information would no longer apply in respect of some proceedings arising under the Health Insurance Act. These proceedings would include prosecutions for failing to produce documents, recovering debts, and non-compliance with the legislation. Noting that the information in question would have been sought for the purposes of the PSR Director's review or a PSR Committee's inquiry, it is appropriate for the material to also be admissible in proceedings that support, or are related to that process, including the recovery of debts.

Under the Health Insurance Act, material must be referred to regulatory bodies, such as the Australian Health Practitioner Regulation Agency (Ahpra) or related Health Practitioner Boards, if the Director, Committee or Determining Authority form the opinion that there is a significant threat to life or health or non-compliance with professional standards.

However, despite the requirement for some information to be referred, the current restrictions on the use of material acquired under the Health Insurance Act may hinder regulatory bodies in taking appropriate regulatory or compliance action in relation to material referred to them.

The Bill would remove restrictions on the use of documents produced to PSR under notice and passed onto Ahpra or a National Board relating to potential threats to life or health, or non-compliance with professional standards. Further, restrictions would not apply to information obtained or generated by Ahpra or a National Board from its own investigation where this investigation was originally triggered by documents produced to PSR under notice.

The amendments are intended to ensure that regulatory bodies can respond appropriately to significant threats to life or health, or non-compliance with professional standards. The role of these regulatory bodies would be frustrated if they were prevented from acting on information that raised risks of harm to patients.

The scope of the proceedings in which the information may be admitted as evidence would be limited to proceedings relevant to either the integrity of the PSR process or health practitioner regulation. The amendments would only operate in respect of criminal or civil proceedings instituted on or after commencement. This would ensure that people providing information to PSR are aware of the circumstances in which the information may be used.

In accordance with the recommendations of the Philip Review, these amendments protect the public interest in ensuring patient safety in health services.

Consultation

The Philip Review consulted with a broad cross-section of the health industry – including health professional bodies, medical defence organisations and government agencies – in making its recommendations. A list of stakeholders consulted is available in the report.

Relevant health professional bodies have been notified of the Bill and relevant Commonwealth agencies, including the Attorney-General's Department and the Department of Social Services were engaged during the development of the proposals. The criminal law division of the Attorney-General's Department indicated the proposed measures relating to the use of information in regulatory proceedings seem reasonable and targeted towards a legitimate policy aim.

Impact on Practitioners and Patients

The measures in the Bill do not adversely affect patients. However, the measures will reduce fraud and non-compliance and e improve the sustainability of Medicare.

The Bill is unlikely to have a significant impact on most practitioners unless they are identified as being engaged in potential non-compliance or fraud. Services will continue to be subject to existing requirements relating to clinical relevance, and requirements relating to Medicare Benefits Schedule item descriptors.

Measures relating to the regulation of therapeutic goods and vaping goods

The Therapeutic Goods Act provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in, or exported from, Australia. It does so, relevantly, by prohibiting the importation, exportation, manufacture and supply of therapeutic goods that are not included in the Australian Register of Therapeutic Goods (Register), unless the goods are exempt from that requirement, or a relevant approval or authority applies under the Therapeutic Goods Act.

The Therapeutic Goods Act also provides for the establishment and maintenance of a national system of controls for the importation, manufacture, supply, commercial

possession, advertising and export of vaping goods. Specifically, the Therapeutic Goods Act prohibits such dealings in vaping goods unless one of a small number of exceptions applies. The intent of these prohibitions is to deter trade in illicit vaping goods, arrest the alarming increase in vaping in Australia, and prevent a new generation of persons being exposed to dangerous chemicals and developing nicotine dependence.

The Therapeutic Goods Act is administered by the Therapeutic Goods Administration (TGA) within the department.

Critical shortages of medicines, biologicals and medical devices in Australia

The Bill would provide the Secretary with an important additional mechanism to address critical shortages of therapeutic goods (principally prescription medicines, biologicals and medical devices). It would do so by allowing the Secretary to approve the temporary importation or supply of therapeutic goods that are not included in the Register (unapproved goods) if the Secretary is satisfied that, among other things, goods that are included in the Register and could act as a substitute *may*, in the reasonably foreseeable future, become unavailable or be in short supply.

This additional mechanism is necessary because the Therapeutic Goods Act relevantly only allows the Secretary to approve the temporary importation or supply of unapproved goods if therapeutic goods that are included in the Register and could act as a substitute *are already* unavailable or in short supply in Australia. This is too late, in many cases, as patients and healthcare providers may have already been significantly impacted by the shortage. Further, because therapeutic goods shortages are frequently global issues, with other countries competing to secure supplies for their citizens, stocks of unapproved goods from overseas may only be available for short periods of time. The measure would therefore enable the Secretary to act more pre-emptively to mitigate the impact of shortages in Australia.

Authorised Prescriber Scheme—circumstances in which authorisation must not be given

The Therapeutic Goods Act establishes the legislative basis for several supply pathways under which persons may, in limited circumstances, access unapproved therapeutic goods. Relevantly, these pathways include:

- the Authorised Prescriber (AP) Scheme, under which the Secretary may authorise a medical practitioner to supply a specified therapeutic good, or specified class of therapeutic goods, to patients with a particular medical condition; and
- the Special Access Scheme (SAS) Category B pathway, under which the Secretary may approve a health practitioner to import or supply a specified therapeutic good for use in the treatment of an individual patient in their care.

Australian Government
Department of Health and Aged Care

The Secretary's power to authorise a medical practitioner under the AP Scheme, or to grant an approval under the SAS Category B pathway, is discretionary. While the Secretary may refuse to provide an AP authority or grant a SAS Category B approval, including where there are emerging safety concerns in relation to the goods that are the subject of the application, such a decision is reviewable.

The Bill would enable regulations to be made under the Therapeutic Goods Act that prescribe circumstances in which the Secretary must not authorise a medical practitioner to supply a specified therapeutic good, or specified class of therapeutic goods, under the AP Scheme. While the Therapeutic Goods Act currently provides for such a mechanism in relation to the SAS Category B pathway, no equivalent mechanism exists in relation to the AP Scheme. In both cases, however, this regulation-making power is critical to ensuring the safety of patients from the use of therapeutic goods that have not been evaluated by the Secretary, and in respect of which there may be serious safety or efficacy concerns, or little to no scientific studies available to support safe use of the goods.

Entry, search and seizure powers—authorised persons and 'persons assisting'

The Bill would amend several provisions in Part 6-2 of the Therapeutic Goods Act, which deal with entry to and searches of premises, including under a warrant, to ensure they are better aligned with the model provisions of the *Regulatory Powers (Standard Provisions) Act 2014* (Regulatory Powers Act).

Greater clarity in relation to the role of 'persons assisting' in the search of premises

Firstly, the Bill would provide greater clarity in relation to the role of a 'person assisting' an authorised person in the exercise or performance of the latter's powers, functions or duties under Part 6-2. The purpose of these amendments would be to principally ensure the powers and functions of persons assisting are appropriately defined and regulated under the Therapeutic Goods Act, and occupiers of premises understand their rights and obligations in relation to such persons.

Broadly, the Bill would:

- insert new section 48AAA, which is modelled on sections 23 and 53 of the Regulatory Powers Act, to set out the powers, functions and duties of persons assisting, and the circumstances in which those powers, functions and duties may be exercised or performed; and
- amend section 48FA, to make it clearer that the occupier of premises at which a warrant is being executed must provide all reasonable facilities to any persons assisting an authorised person with the execution of the warrant.

Australian Government
Department of Health and Aged Care

Improved flexibility in relation to the execution of certain warrants

Secondly, the Bill would provide improved flexibility to authorised persons executing a warrant under section 50 of the Therapeutic Goods Act (section 50 warrant). It would do so by enabling an authorised person executing a section 50 warrant to pause the execution of the warrant and depart the premises temporarily for as long as necessary (including overnight, for example), provided at least one other authorised person, or person assisting the authorised persons, remains at the premises for the entirety of the first authorised person's absence.

This measure is necessary as section 48AA currently precludes an authorised person from resuming the execution of a section 50 warrant if that person was absent from the premises for longer than one hour, or 12 hours in an emergency. This is the case even if other authorised persons or persons assisting remained at the premises for the entirety of the first authorised person's absence. The inflexibility of these arrangements impacts the regulator's ability to effectively investigate suspected offences against, or contraventions of, the Therapeutic Goods Act, particularly where it is necessary for an authorised person to temporarily leave the premises for longer than an hour (including to collect necessary equipment to aid an investigation or to sleep).

The effect of this measure would be to more closely align section 48AA of the Therapeutic Goods Act with section 59 of the Regulatory Powers Act. This is appropriate to ensure increased consistency for the exercise of compliance and enforcement powers under Commonwealth legislation.

Improved flexibility and effectiveness of compliance and enforcement powers

Broadened application of forfeiture arrangements

Section 52AAA of the Therapeutic Goods Act allows for the forfeiture of things seized under a section 50 warrant, to the Commonwealth, if the Secretary believes on reasonable grounds that:

- broadly, the thing has been dealt with in a way that contravenes the Therapeutic Goods Act, or an instrument made under that Act; or
- a requirement under the Therapeutic Goods Act, or an instrument made under that Act, has not been complied with in relation to the thing.

The power is intended to support the regulator's ability to efficiently disrupt the trafficking of unlawful and unsafe therapeutic goods and vaping goods.
Section 52AAA only applies in relation to things seized under a section 50 warrant. The limited application of section 52AAA is undesirable because there are also other provisions in Part 6-2 of the Therapeutic Goods Act under which authorised persons may seize

unlawful or unsafe goods, including, for example, section 46B (which applies to things that may be seized on public health grounds).

Consequently, the Bill would amend section 52AAA to extend the forfeiture arrangements to things seized under any seizure provision in Part 6-2 of the Therapeutic Goods Act.

Improved availability of enforceable directions

Section 42YT of the Therapeutic Goods Act provides that the Secretary may give enforceable directions to a person, requiring them to do certain things in relation to goods (including destruction or disposal), if the Secretary believes, on reasonable grounds, that:

- the person is not complying with the Therapeutic Goods Act, or an instrument made under that Act, in relation to those goods; and
- it is necessary to give the direction to protect the health and safety of humans.

It is considered the second pre-condition listed above may impose too high a burden on the Secretary to exercise the power to give directions under section 42YT. This is because, in effect, the second pre-condition requires the Secretary to believe that the direction is the only practical means of protecting the health and safety of humans. This is particularly problematic in the context of goods where there may only be limited or emerging evidence of adverse health effects. In such circumstances, it is unlikely the Secretary could form a reasonable belief that a direction under section 42YT is 'necessary' to protect the health and safety of humans.

Consequently, the Bill would amend section 42YT of the Therapeutic Goods Act to substitute the second pre-condition with a new pre-condition requiring the Secretary to believe, on reasonable grounds, that it is 'in the interests of public health or safety' to give the person a direction under that provision. This measure would create an appropriately high threshold for the exercise of the power under section 42YT, while still practically permitting the Secretary to give directions under that provision when it is in the interests of public health or safety.

Minor amendments to the Tobacco Act

The Bill also amends the Tobacco Act to make minor amendments identified as necessary to ensure smooth and consistent operation of that Act. These include:

- providing for regulations to be made to support phase in and out of regulated tobacco product requirements;
- a clarification around who can be an "authorised officer" under the Tobacco Act;
- ensuring corporations are captured by tobacco and e-cigarette sponsorship prohibitions; and

Australian Government
Department of Health and Aged Care

- harmonising the interaction with the Therapeutic Goods Act vaping advertising provisions.

Conclusion

The Bill would improve the department's ability to respond to and address non-compliance with Medicare requirements, recover funds, deter inappropriate practice, and support existing regulatory schemes.

The Bill would also implement a number of important measures under the Therapeutic Goods Act. These include measures to enhance the Secretary's ability to address critical shortages of therapeutic goods in Australia, protect patients from unapproved therapeutic goods in respect of which there may be serious safety or efficacy concerns, and improve the flexibility and effectiveness of compliance and enforcement activities undertaken in relation to therapeutic goods and vaping goods.

The Bill would support effective implementation of the Tobacco Act and harmonisation with the Therapeutic Goods Act in respect of e-cigarette and vaping advertising.