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31.08.2026

PBS Listing, Pricing and Policy Branch
Department of Health, Disability & Ageing
PO Box 9848
Canberra ACT 2601

Via email: PBSOperationalPolicy@health.gov.au

Re: Remaking the *National Health (Pharmaceutical Benefits) Regulations 2017* (PB Regulations)

The Royal Australasian College of Physicians (the RACP) appreciates the opportunity to comment on the Department of Health, Disability & Ageing's proposed changes to the PB Regulations, to be introduced on the sunsetting of existing legislative instruments on 1 April 2027.

We note that several of the proposed amendments will affect physicians who prescribe PBS-listed medicines. A substantial number of the proposed amendments relevant to prescribing physicians relate to administrative compliance requirements, including prescription drafting requirements, prescriber bag orders, record keeping obligations, repeat authorisations, supply arrangements and associated documentation requirements. While several amendments appear to clarify or formalise existing practice, others introduce revised technical requirements or strengthen existing compliance provisions, including significant increases in penalties for non-compliance.

Physicians work in increasingly complex and time-poor clinical and administrative environments and compliance with PBS requirements often depends on understanding detailed legislative, procedural and documentation rules that can be easily missed or overlooked. We are concerned that the revisions will treat instances of administrative errors and deliberate disregard of regulatory obligation in the same manner. The RACP strongly supports efforts to promote PBS integrity, balanced with clear, proportionate and risk-managed approaches.

A proportionate compliance framework should distinguish between deliberate misconduct and inadvertent administrative error. Educational and corrective responses should remain the preferred approach for non-compliance arising from misunderstanding, awareness gaps, or minor administrative oversight.

The compliance framework should also embed transparent review mechanisms, reconsideration processes and appeal pathways as part of implementation activities. Education should especially be prioritised ahead of blunt punitive action in the transitional phase, recognising the heightened potential for uncertainty and errors during this period.

While we appreciate the overview of the proposed changes is insightful, the consultation materials for the regulations offer no further information on planned practitioner education, tools or implementation supports. We strongly recommend a comprehensive communication and education strategy, given the technical nature of many of the changes. Physicians cannot reasonably be expected to identify and interpret all legislative amendments without targeted guidance and practical implementation support, provided with significant lead time. Early career physicians would particularly benefit from such support.

We welcome the opportunity to promote information on the upcoming changes to the PB Regulations to Fellows and trainees across Australia through RACP communication channels.

Please contact Peter Lalli, Senior Policy & Advocacy Officer via email: Peter.Lalli@racp.edu.au for further information.