

RESTRICTIVE PRACTICES IN RESIDENTIAL AGED CARE IN AUSTRALIA

BACKGROUND PAPER 4

MAY 2019

The Royal Commission into Aged Care Quality and Safety was established on 8 October 2018 by the Governor-General of the Commonwealth of Australia, His Excellency General the Honourable Sir Peter Cosgrove AK MC (Retd). Replacement Letters Patent were issued on 6 December 2018.

The Honourable Richard Tracey AM RFD QC and Ms Lynelle Briggs AO have been appointed as Royal Commissioners. They are required to provide an interim report by 31 October 2019, and a final report by 30 April 2020.

The Royal Commission intends to release consultation, research and background papers. This background paper has been prepared by staff of the Office of the Royal Commission, for the information of Commissioners and the public. The views expressed in this paper are not necessarily the views of the Commissioners.

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Introduction

This paper provides a high-level introduction to restrictive practices in residential aged care in Australia. It has been prepared by staff of the Office of the Royal Commission into Aged Care Quality and Safety but does not represent a direction or position of the Royal Commission in relation to this area. Any views expressed are not necessarily the views of the Commissioners.

The use of restrictive practices in residential aged care in Australia is contentious. There is significant public interest in the issue of restraint and ways to reduce or avoid it. Numerous media reports and inquiries have highlighted accounts of the misuse or overuse of physical restraint and psychotropic medication.¹ This includes personal accounts from members of the public about residents being physically restrained frequently, or for long periods of time, or restrained without consent.²

Restrictive practices can elicit concern for a number of reasons. Fundamentally, they impact on the liberty and dignity of the care recipient.³ In circumstances where they are not absolutely necessary, their use is likely to sit uncomfortably for many.⁴ Their use without lawful consent may infringe the resident's legal rights and constitute a civil or criminal offence, such as assault or false imprisonment, although there are very few cases in Australia where a criminal or civil complaint has been pursued to challenge the use of a restraint in an aged care setting.⁵

Physical and chemical restraint can have significant adverse effects on a resident, both physically and psychologically. There are also fundamental questions about their effectiveness.

See, for example, A Connolly, *Who Cares?: A special two-part investigation of the failings in aged care*, Australian Broadcasting Commission (ABC), 20 September 2018, viewed 26 April 2019, https://www.abc.net.au/news/2019–01–16/elderly-dementia-patients-given-anti-psychotics-and-restrained/10621658; https://www.abc.net.au/radionational/programs/lawreport/2018–04–

24/9679098; https://www.abc.net.au/4corners/who-cares/10258290.

L Martin, Nursing homes turning residents into 'zombies', aged care royal commission to hear, The Guardian Australia, 15 January 2019, viewed 26 April 2019,

https://www.theguardian.com/australia-news/2019/jan/15/nursing-homes-turning-residents-into-zombies-aged-care-royal-commission-to-hear; https://www.9now.com.au/a-current-affair/2019/clip-cjs038b8v000e0glhmzjr6m12.

A Connolly and J Stewart, *Aged care home resident strapped to chair for total of 14 hours in one day*, ABC, 16 January 2019, viewed 26 April 2019, https://www.abc.net.au/news/2019–01–16/elderly-dementia-patients-given-anti-psychotics-and-restrained/10621658.

³ Australian Law Reform Commission, *Elder Abuse—A National Legal Response*, Report No 131, 2017, pp 142–143.

See, for example, J Ibrahim, *Physical restraint doesn't protect patients—there are better alternative,* The Conversation, 11 February 2019, viewed 26 April 2019, https://theconversation.com/physical-restraint-doesnt-protect-patients-there-are-better-alternatives-111060.

Office of the Public Advocate Qld, Legal frameworks for the use of restrictive practices in residential aged care: an analysis of Australian and international jurisdictions, 2017, p 3. See, for example, Skyllas v Retirement Care Australia (Preston) Pty Ltd [2006] VSC 409; Saitta Pty Ltd v Secretary, Department of Health and Ageing (2008) 105 ALD 55; BC v The Public Advocate & ors [2018] SASC 193.

Some inquiries have recommended greater regulation of restrictive practices in aged care in Australia.⁶ In April 2019, the Minister for Senior Australians and Aged Care, the Hon Ken Wyatt AM, MP, introduced new requirements concerning the use of restraint in residential aged care services in Australia. These requirements apply to government-funded aged care providers under the *Aged Care Act 1997* (Cth) from 1 July 2019.

What are restrictive practices?

The term restrictive practices refers to activities or interventions, either physical or pharmacological, that have the effect of restricting a person's free movement or ability to make decisions. Restrictive practices are commonly referred to in the context of residential aged care as practices that control the behaviour of a resident, which may occur with the intention of reducing risks to a resident or others.

Physical restrictive practices

Common restrictive practices in residential aged care that are physical in nature include:

- clasping a person's hands or feet to stop them from moving;
- applying lap belts, leg, wrist, ankle, or vest restraints;
- attaching bed rails, locking over bed or chair tray tables;
- seating residents in chairs with deep seats, or rockers and recliners, that the resident cannot stand up from, or removing their mobility aids.

Restrictive practices may also include confining a person in a residential facility or specialised unit.⁷

Pharmacological restrictive practices

Particular medicines prescribed for residents in residential aged care can have the effect of restricting their movements or ability to make decisions. Medications that cause sedation such as mirtazapine, benzodiazepines and opioids prescribed for pain relief have potential to have a restrictive effect. Opioids such as oxycodone, oxycodone plus naloxone, buprenorphine patch, and fentanyl patch have the highest utilisation rate in people aged over 75 years (per 1000 population aged 75 years and older).8

The most common type of medications that can have the effect of restricting a person's movements or ability to make decisions are psychotropic medications, capable of affecting

Australian Law Reform Commission, Equality, Capacity and Disability in Commonwealth Laws. Report 124, 2014, p 19. Australian Law Reform Commission, above n 3, p 11.

K Carnell and R Paterson, *Review of National Aged Care Quality Regulatory Processes.* 2017, p xii.

Australian Law Reform Commission, above n 3, p 143.
Department of Health and Ageing, *Decision-Making Tool: Supporting a restraint free environment in residential aged care*, 2012, pp 24–25.

Brug Utilisation Sub-Committee, Opioid Analgesics: Overview Drug Utilisation Sub-Committee. Department of Health, October 2014, viewed 19 April 2019, http://www.pbs.gov.au/industry/listing/participants/public-release-docs/opioids/opioids-dusc-prd-2014–10-final.pdf.

the mind, emotions and behaviours of a person.⁹ They include stimulants, antidepressants, antipsychotics, mood stabilizers and anti-anxiety agents. In aged care, they are most commonly prescribed in response to exhibited behavioural or psychological symptoms of dementia (commonly referred to as BPSD or neuropsychiatric symptoms).

Modern psychotropic medications have been around since about the 1950s when the first antipsychotics, monoamine-oxidase inhibitor antidepressants, and anxiolytic/hypnotic sedatives, called benzodiazepines were developed. These medicines revolutionised the treatment of mental illness and were often safer than older medicines such as barbiturates, prominent in the first half of the 1900s. However, they were still associated with potentially severe side effects and could be fatal in the case of overdose. The development of these medicines gave way to a better understanding of the underlying biochemical disturbances associated with mental illness. This was used to develop newer, more targeted drugs with less risk for extrapyramidal side effects (i.e. involuntary and uncontrollable movements including twitches, jerking, twisting, restlessness), including the antipsychotics that currently dominate the Australian market, such as quetiapine, olanzapine and risperidone. A list of the most common psychotropic and other drugs relevant to chemical restraint and aged care, together with their clinical indications, is at the Appendix.

Prescription and administration of psychotropic medications may occur for the purposes of treating a resident with a diagnosed illness or condition. Use of such medications may not be recognised as restrictive practices, or restraint, unless the apparent purpose of using the medication is to restrict the resident's movement or ability to make decisions, as opposed to treatment of a particular illness.

Variations in defining physical and chemical restraint

Definitions of physical and chemical 'restraint' and 'restrictive practices' used in legislation, guidance, research papers and reports vary in terms of: the terminology used; the precise categorisation of restraints; the breadth of activities recognised as restraint; and the relevance of the purpose of the activity in determining whether a practice constitutes a restraint. For example:

The recent Quality of Care Amendment (Minimising the Use of Restraints) Principles 2019 effective from 1 July 2019 broadly define physical restraint as any practice, device or action (other than chemical restraint or medication used for treatment of a mental disorder, physical illness or condition) that interferes with a 'consumer's' ability to make a decision or restricts a consumer's free movement.¹²

Chemical restraint is, however, characterised by the purposes for which a medication is used. Medication that has been prescribed for the purposes of

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Farlex, *Farlex Partner Medical Dictionary*, United Sates, 2012, viewed 24 April 2019, www.medical-dictionary.thefreedictionary.com/psychotropic.

T M Millhouse and J H Porter, 'A brief history of the development of antidepressant drugs: From monoamines to glutamate' (2015) 23 Expert Clinical Psychopharmacology 1.
J Bryan, Landmark drugs: the discovery of benzodiazepines and the adverse publicity that followed, the Pharmaceutical Journal, United Kingdom, 19 September 2009, viewed 12 April 2019, www.pharmaceutical-journal.com/opinion/comment/landmark-drugs-the-discovery-of-benzodiazepines-and-the-adverse-publicity-that-followed/10978453.article?firstPass=false.
T Ban, 'Fifty years chlorpromazine: a historical perspective' (2007) 3 Neuropsychiatric Disease and Treatment 495.

Quetiapine, Olanzapine and Risperidone are the highest PBS dispensed antipsychotic prescriptions in recent years (2017–18): Department of Health, *Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme Section 85 Date of Supply Data*, 2019, viewed 26 April 2019, www.pbs.gov.au/info/statistics/dos-and-dop/dos-and-dop.

¹² Quality of Care Amendment (Minimising the Use of Restraints) Principles 2019, section 4.

treatment of a mental disorder, physical illness or condition is not characterised as restraint for the purposes of the Principles.

• The Department of Health's *Decision-Making Tool: Supporting a Restraint Free Environment in Residential Aged Care 2012* states that restraint is 'any aversive practice, device or action that interferes with any person's ability to make a decision or which restricts their free movement'. 13

Physical restraint is described within the guidance as 'the intentional restriction of a resident's voluntary movement or behaviour by the use of a device, or removal of mobility aids, or physical force for behavioural purposes'.¹⁴

The guidance as to what constitutes chemical restraint requires consideration of whether the medication is necessary for the treatment of an identified medical condition. ¹⁵ This might require consideration of the specific medication used, dose and dosing schedule. ^{16,17,18}

• The Department of Social Services' *National Framework for Reducing and Eliminating the Use of Restrictive Practices in the Disability Service Sector* defines restrictive practices as 'any intervention that has the effect of restricting the rights or freedom of movement of a person with disability with the primary purpose of protecting the person or others from harm'.¹⁹

Physical restraint is defined as the sustained or prolonged use or action of physical force to prevent, restrict or subdue movement of a person's body, or part of their body, for the primary purpose of influencing a person's behaviour.²⁰

Chemical restraint is defined as the use of medication or chemical substance for the primary purpose of influencing a person's behaviour or movement, but does not include the use of medication prescribed by a medical practitioner for the treatment, or to enable treatment, of a diagnosed mental disorder, a physical illness or physical condition.²¹

 The Australian Commission on Safety and Quality in Health Care's National Safety and Quality Health Service Standards, 2017 defines restraint more narrowly as the 'restriction of an individual's freedom of movement by physical or mechanical means'.²² It contends that there is a lack of consensus on the definition of chemical/pharmacological restraint because of difficulties in determining whether a clinician's intent is primarily to treat a person's symptoms or to control their behaviour.²³

Department of Health and Ageing, above n 7, p 1.

¹⁴ Ibid, p 24.

¹⁵ Ibid, pp 25–26.

The Royal Australian & New Zealand College of Psychiatrists, Professional Practice Guideline 10— Antipsychotic medications as a treatment of behavioural and psychological symptoms of dementia, August 2016.

¹⁷ Therapeutic Guidelines Ltd (eTG April 2019 edition).

¹⁸ Australian Medicines Handbook, 2019.

Department of Social Services, *National Framework for Reducing and Eliminating the Use of Restrictive Practices in the Disability Service Sector*, 2013, p 4.

²⁰ Ibid, p 5.

²¹ Ibid, p 5.

Australian Commission on Safety and Quality in Health Care, National Safety and Quality Health Service Standards, 2017, p 75.
Australian Commission on Safety and Quality in Health Care, National Safety and Quality Health

Australian Commission on Safety and Quality in Health Care, *National Safety and Quality Health Service Standards: Guide for Hospitals*, 2017, p 322.

Australian Commission on Safety and Quality in Health Care, *National Safety and Quality Health Service Standards guide for multi-purpose services and small hospitals*, 2017, p 172.

• The Department of Health's National Standards for Mental Health Services, 2010 defines restraint as a 'restrictive intervention that relies on external controls to limit the movement or response of a person'.24

Variations in definitions of restraint reflect challenges in conceptualising and identifying restraint in practice. For instance, inappropriate prescription or administration of medication might not be recognised as restraint if it has been prescribed to treat a diagnosed illness or condition. Recognising restraint as a practice intended to avoid harm may conflate the justification for restraint with the impact on the resident and obscure the significance of perceptions of risk, including the risks associated with restraint itself. Secluding or confining a person to a residence or a locked dementia unit may not be recognised as restraint, although such practices can significantly inhibit a resident's liberty to move within or outside the residence.

The effects of restrictive practices

Physical restraint

While in certain circumstances, physical restraint may be necessary to mitigate risks to a resident or others in an emergency, empirical evidence demonstrates that restrictive practices can cause death, as well as other serious physical and psychological consequences that may increase morbidity, or expedite the dying process.²⁵ Adverse impacts of physical restraint on a person can include:

• fear, shame, anxiety, loss of dignity²⁶, agitation²⁷, depression²⁸, lower cognitive performance:29

²⁴ Department of Health, *National Standards for Mental Health Services*, 2010, p 40.

²⁵ N Bellenger, J Ibrahim et al., 'The Nature and Extent of Physical Restraint-related Deaths in Nursing Homes: A systematic review' (2018) 30(7) Journal of Aging and Health 1031. C Peisah, E Skladzien, The use of restraints and psychotropic medications in people with dementia: A Report for Alzheimer's Australia, Report No 38, 2014, p 12 citing W Tang, Y Chow and S Koh, 'The effectiveness of physical restraints in reducing falls among adults in acute care hospitals and nursing homes: a systematic review' (2012) 10 (5) The JBI Database of Systematic Reviews and Implementation Reports 307.

²⁶ C Peisah, E Skladzien, above n 25, p 12. M Rakhmatullina, A Taub, T Jacob, 'Morbidity and mortality associated with the use of restraints; a review of the literature' (2003) 84(4) The Psychiatric Quarterly 449.

²⁷ C Gastmans, K Milisen, 'Use of physical restraint in nursing homes: clinical and ethical considerations' (2006) 32 Journal of Medical Ethics 148. N Castle, 'Mental health outcomes and physical restraint in nursing homes' (2006) 33 Administration and Policy in Mental Health 696.

²⁸ Ibid.

²⁹ J Enberg, N Castle, D McCaffrey, 'Physical restraint initiation in nursing homes and subsequent resident health' (2008) 48 Gentrologist 441. N Castle, above n 27.

- bruising, direct skin injuries³⁰, pressure injuries³¹, contractures³², respiratory complications³³, urinary and faecal incontinence and constipation³⁴, under nutrition³⁵, reduced mobility and increased dependence in activities of daily living³⁶, impaired muscle strength and balance³⁷, reduced cardiovascular endurance;³⁸
- serious injury and mortality.³⁹

There are also questions about the effectiveness of physical restraint in reducing or avoiding harm. For example, a recent study into the nature and extent of physical restraint-related deaths in nursing homes affirmed the view that individuals still experience falls even when restrained to prevent them.⁴⁰ The literature also suggests that physical restraints are not effective in preventing serious injury as a consequence of aggressive behaviour. In many cases, the agitation, discomfort and anxiety of the resident is only increased.⁴¹

Some academics argue that there is sufficient empirical evidence to support the idea that, in many cases, physical restraint causes more harm than benefit.⁴²

Chemical restraint

Pharmacological approaches for the treatment of the behavioural and psychological symptoms of dementia may be effective for some people with severe agitation and aggression associated with risk of harm, delusions and hallucinations or comorbid pre-existing mental health conditions.⁴³ However, the use of psychotropic medicines is also associated with increased risk of serious adverse events, and their overuse or misuse may have significant impacts on a person's health, including:

- sedation, gait disturbances and increased risk of falls and fractures;
- · urinary tract infections or incontinence;

D Evans, J Wood and L Lambert, above n 30.

D Evans, J Wood, L Lambert, 'Patient injury and physical restraint devices: a systematic review', (2003) 41(3) *Journal of Advanced Nursing* 274.

³¹ C Gastmans, K Milisen, above n 27.

N Castle, J Engberg, 'The health consequences of using physical restraints in nursing homes' (2009) 47 (11) *Medical Care* 1164.

³² Ibid.

³³ C Gastmans, K Milisen, above n 27.

³⁴ C Peisah, E Skladzien, above n 25, p 11.

³⁵ C Gastmans, K Milisen, above n 27.

³⁶ J Enberg, N Castle, D McCaffrey, above n 29.

C Gastmans, K Milisen, above n 27.

N Castle, J Engberg, above n 31.

³⁷ A Gillis, B MacDonald, 'Deconditioning in the hospitalized elderly' (2005) 101(6) *The Canadian Nurse* 16.

C Gastmans, K Milisen, above n 27.

³⁸ C Gastmans, K Milisen, above n 27.

³⁹ Ibid.

B Karger, T Fracasso, H Pfeiffer, 'Fatalities related to physical restraint devices—Asphyxia is a common finding' (2008) 178 *Forensic Science International* 178.

E Bellenger, J Ibrahim, L Bugeja, B Kennedy, 'Physical restraint deaths in a 13 year national cohort of nursing home residents' (2017) 46 (4) *Age and Ageing* 688.

⁴⁰ N Bellenger, J Ibrahim et al., above n 25.

⁴¹ C Gastmans, K Milisen, above n 27.

⁴² Ibid.

⁴³ The Royal Australian & New Zealand College of Psychiatrists, above n 16.

- increased cognitive impairment and confusion;
- constipation and associated risk for faecal impaction and bowel obstruction;
- increased risk for extrapyramidal side effects (drug-induced movement disorders including restlessness and agitation);
- increased risk of respiratory complications (such as pneumonia), stroke and heart rhythm abnormalities, cerebrovascular events (including stroke) and increased risk of death.⁴⁴

In at least one recent coronial inquiry in Victoria, an inappropriate oxazepam (a benzodiazepine) regime prescribed to a person living with dementia in a residential aged care facility was linked to a number of falls, causing multiple fractures, and was found to have contributed to her physical decline and death. The Coroner referred his findings to the (then) Australian Aged Care Quality Agency and to the Royal Australian College of General Practitioners relating to, among other things, the inappropriate prescription and administration of the medication oxazepam on an 'as required' basis. There is a body of literature establishing that long-term use of benzodiazepines is associated with significant long-term cognitive impairment and increased risk of dementia.

In the United States, the Food and Drug Administration issued a safety alert in 2005 concerning the increased risk of death for dementia patients prescribed antipsychotic drugs.⁴⁷

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dementia: Meta-analysis of randomised, placebo controlled trials' (2006) 14(3) *American Journal of Geriatric Psychiatry*, 191.

L Hien, R Cumming, I Cameron, J Chen, S Lord, L March, J Schwarz, D Le Couteur, P Sambrook, 'Atypical antipsychotic mediations and risk of falls in residents of aged care facilities' (2005) 58(3) *Journal of the American Geriatric Society*, 1290.

C Ballard, M Hanney, M Theodoulou, S Douglas, R McShane, K Kossakowsk, R Gill, E Juszczak, L M Yu, R Jacoby, 'The dementia antipsychotic withdrawal trial (DART-AD): long-term follow up of a randomised placebo-controlled trial' (2009b) 8(2) *Lancet Neurology* 8(2) 151.

C Peisah, E Skladzien, above n 25, pp 12, 19.

Inquiry into the death of Margaret Elizabeth Barton [2019] https://www.coronerscourt.vic.gov.au/sites/default/files/2019–02/MargaretBarton 152715.pdf.

S Billioti de Gage, B Begaud, F Bazin, et al., 'Benzodiazepine use and risk of dementia: Prospective population based study.' (2012) *The BMJ* 345:e6231.

C S Wu, S C Wang, I S Chang, K M Lin, 'The association between dementia and long-term use of benzodiazepine in the elderly: Nested case-control study using claims data' (2009) 17(7) *The American Journal of Geriatric Psychiatry* 614.

J Gallacher, P Elwood, J Pickering, et al., 'Benzodiazepine use and risk of dementia: Evidence from the Caerphilly Prospective Study (CaPS)' (2012) 66(10), *Journal of Epidemiology and Community Health* 869.

⁴⁷ United States Food and Drug Administration, *FDA Public Health Advisory: Deaths with antipsychotics in elderly patients with behavioural disturbances*, 11 April 2005.

⁴⁴ Ibid.

S Dyer, S Harrison, K Laver, C Whitehead and M Crotty, 'An overview of systematic reviews of pharmacological and non-pharmacological interventions of the treatment of behavioural and psychological symptoms of dementia' (2018) 30(3) *International Psychogeriatric* 295.

L Schneider, K Dagerman, P Insel, 'Efficacy and adverse effects of atypical antipsychotics for dementia: Meta-analysis of randomised, placebo controlled trials' (2006) 14(3) *American Journal of the property of the property*

Can restrictive practices be reduced or avoided?

Whether either physical or pharmacological restrictive practices are necessary in residential aged care is contentious. Some submissions to the Australian Law Reform Commission's enquiry on Elder Abuse, for example, expressed the view that restraint in residential care should be a last resort, but is sometimes necessary to protect the resident or staff. Others questioned whether restrictive practices are ever necessary, advocating that the focus should instead be on alternatives that reflect personalised care. Many raised concerns about their overuse.⁴⁸

In practice, physical and pharmacological restrictive practices are often used on people with cognitive impairment who exhibit challenging behaviour, including people exhibiting the behavioural and psychological symptoms of dementia. Behaviours associated with these symptoms that may cause concern include agitation or extreme restlessness, physical and verbal aggression, wandering, and social and/or sexual disinhibition. The psychological symptoms present in someone with dementia may include delusions, hallucinations, apathy, depression and anxiety. These symptoms are unique to the person and their circumstances and may be made worse by contributing factors such as pain, fear, feelings of being threatened or stress associated with confusing environments and side effects of medications that contribute to anticholinergic burden, sedation, delirium and movement disorders. Background Paper 3—Dementia in Australia: nature, prevalence and care includes further discussion about the behavioural and psychological symptoms of dementia.

There is an emerging body of evidence and guidance on strategies and non-pharmacological interventions to negate or mitigate the need for restraint by managing the underlying causes of challenging behaviour. Some of the key considerations emerging from the literature include:

• Environmental, e.g. measures to reduce risk of falls or confusion such as non-slip flooring and footwear, improved lighting, signage, appropriate beds and seating, mobility aids, reduced environmental noise, alarm systems.⁵¹ One international study indicated that in terms of the layout of the residential aged care facility, the significant factors include keeping a small number of residents in each living area, adopting a straight layout of the circulation system without any changes in direction and only one dining room.⁵²

Organisation for Economic Cooperation and Development Health Policy Studies, Care Needed: Improving the Lives of People with Dementia, 12 June 2018.

⁴⁸ Australian Law Reform Commission, above n 3, p 144.

Cognitive Decline Partnership Centre, Clinical Practice Guidelines and Principles of Care for People with Dementia, 2016, pp 15–17.

^{&#}x27;Anticholinergic burden' refers to the cumulative effect of using multiple medications that block the effects of the neurotransmitter acetylcholine in the body and is associated with significant adverse side effects including blurred vision, constipation, delirium, confusion and cognitive impairment.

Day, D Carreon, C Stump, 'The Therapeutic Design of Environments for people with dementia: A review of Empirical Research' (2000) 40(4) *Gerontologist* 397.

J Kwok-Wai Wong, M Skitmore, L Buys, K Wang, 'The effects of the indoor environment of residential care homes on dementia suffers in Hong Kong: a critical incident technique approach' (2014) 73 *Building and Environment* 32.

G Marquardt, P Schmieg,' Dementia-Friendly Architecture: Environments That Facilitate Wayfinding in Nursing Homes' (2009) 24(4) *American Journal of Alzheimer's Disease & Other Dementias* 333.

- Psychosocial, e.g. engaging familiar staff, provision of sensory aids and appropriate sensory stimulation, therapies and activities such as occupational therapy and activities using overlearned skills (such as gardening or folding laundry), therapeutic touch, and companionship.⁵³
- Care approach, e.g. individualised routines, increased supervision and staff interaction, appropriate staffing level and mix, regular evaluation and monitoring of conditions affecting behaviour.⁵⁴
- Physiological, e.g. comprehensive medical examination and review of medication (including medication that may contribute to worsening cognitive function, restlessness and agitation⁵⁵), nutrition and hydration management, treating infections, pain management.⁵⁶

There are requirements to attempt non-pharmacological interventions before prescribing any psychotropic medications to manage challenging behaviours. For example, when prescribing risperidone, a medication approved in Australia and New Zealand for the use of behavioural disturbances associated with Alzheimer's type dementia, the Pharmaceutical Benefits Scheme (PBS) requires that non-pharmacological methods of treatment be tried first. Only after the patient has failed to respond, can the medication be validly prescribed under that scheme.⁵⁷

The Royal Australian and New Zealand College of Psychiatrists' *Professional Practice Guideline 10: Antipsychotic medications as a treatment of behavioural and psychological symptoms of dementia* states that the first line approach to management of the behavioural and psychological symptoms of dementia is a person-centred, psychosocial multidisciplinary treatment plan. Use of antipsychotic medications are recommended when symptoms are psychotic in nature, unresponsive to psychosocial interventions or there is a severe and complex risk of harm. They are not recommended for symptoms such as wandering, undressing, inappropriate voiding, verbal aggression or screaming.⁵⁸

Even when psychotropic medication is prescribed, the available literature suggests that non-pharmacological strategies, such as social interaction interventions, be co-administered to mitigate any potential negative effects of the latter on behavioural and psychological symptoms.⁵⁹

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K Burns, R Jayasinha, R Tsang, H Brodaty, *Behaviour Management: A Guide to Good Practice Managing Behavioural and Psychological Symptoms of Dementia (BPSD)* 2012.

⁵⁴ Ihid

Department of Veterans' Affairs, Veterans' Mates—Helping your patients with cognitive impairment to live well at home. Canberra, March 2019, viewed 19 April 2019, https://www.veteransmates.net.au/topic-54-therapeutic-brief.

K Burns, R Jayasinha, R Tsang, H Brodaty, above n 53.
 See also C Peisah, E Skladzien, above n 25, p 14.
 Department of Health and Ageing, above n 7, p 3.
 Australian Commission on Safety and Quality in Health Care, *Preventing Falls and Harm from Falls*

in Older People: Best practice Guidelines for Australian Residential Aged Care Facilities, 2009.
 Department of Health, Pharmaceutical Benefits Scheme website, viewed 26 April 2019,

be partment of Health, Pharmaceutical Benefits Scheme website, viewed 26 April 2019, www.pbs.gov.au/medicine/item/1842Y-1846E-3169T-3170W-3171X-3172Y-8100H-8780D-8781E-8782F-8787L-8789N-8869T-9079W-9293D.

⁵⁸ Royal Australian and New Zealand College of Psychiatrists, above n 16.

A P Rajkumar, C Ballard, J Fossey, A Corbett, B Woods, M Orrell, et al., 'Apathy and its response to antipsychotic review and nonpharmacological interventions in people with dementia living in nursing homes: WHELD, a factorial cluster randomized controlled trial' (2016) 18(7) *Journal of American Medical Directors Association* 741.

C Ballard, M Orrell, S YongZhong, E Moniz-Cook, J Stafford, R Whittaker, et al., 'Impact of antipsychotic review and nonpharmacological intervention on antipsychotic use, neuropsychiatric symptoms, and mortality in people with dementia living in nursing homes: a factorial cluster-

Despite the emerging evidence about non-pharmacological interventions to negate or mitigate the need for restraint, research indicates that barriers to their use in aged care facilities include:⁶⁰

- perceptions about safety, fear of resident injury and legal concerns;⁶¹
- residential facility characteristics such as staff and resource constraints and organisational culture;⁶²
- lack of knowledge about effects of restraints and alternative practices;⁶³
- beliefs and expectations of staff, family and residents, including a paternalistic attitude towards older people;⁶⁴
- inadequate review;⁶⁵
- communication barriers.⁶⁶

A submission from the Australian and New Zealand Society for Geriatric Medicine to the Australian Law Reform Commission's enquiry on Elder Abuse indicated that inappropriate use of drugs was a practice 'driven by lack of skills and knowledge as well as staffing numbers.'⁶⁷ In another earlier enquiry it was observed further barriers to reducing or avoiding restraint in residential aged care may include funding models, complexity of the care needs of residents and inadequate collaboration between health professionals and residential aged care staff.⁶⁸

A range of studies have considered the effectiveness of organisational interventions aimed at reducing physical and chemical restraint, including education programs, consultancy support,

randomized controlled trial by the well-being and health for people with dementia (WHELD) program' (2016) 173(1) *American Journal of Psychiatry* 252.

⁶⁰ C Peisah, E Skladzien, above n 25, pp 11, 23 citing K Moor, B Haralambous (2007) 'Barriers to reducing the use of restraints in residential elder care facilities' (2007) 58 *Journal of Advanced Nursing*, 532.

J Agens, 'Chemical and physical restrain in the older person' (2010) 3 *British Journal of Medical Practitioners*, 302.

Y Jeon, T Merlyn, L Chenoweth, 'Leadership and management in the aged care sector: a narrative synthesis' (2010) 29(2), *Australasian Journal of Ageing* 54.

See also K Carnell and R Paterson, above n 6, p 120.

⁶¹ K Moore, B Haralambous, 'Barriers to reducing the use of restraints in residential elder care facilities' (2007) 58 *Journal of Advanced Nursing*, 532.

C Lane, A Harrington 'The factors that influence nurses use of physical restraint: A thematic literature review' (2011) 17 *International Journal of Nursing Practice* 195.

R Nay, S Koch 'Overcoming restraint use: Examining barriers in Australian aged care facilities' (2006) 32(1) *Journal of Gentrological Nursing* 33.

⁶² K Moore, B Haralambous, above n 61.

C Lane, A Harrington 'The factors that influence nurses use of physical restraint: A thematic literature review' (2011) 17 *International Journal of Nursing Practice* 195.

R Nay, S Koch 'Overcoming restraint use: Examining barriers in Australian aged care facilities' (2006) 32(1) *Journal of Gentrological Nursing* 33.

N Bellenger, J Ibrahim et al., above n 25.

⁶³ K Moore, B Haralambous, above n 61.

R Nay, S Koch 'Overcoming restraint use: Examining barriers in Australian aged care facilities' (2006) 32(1) *Journal of Gentrological Nursing*, 33.

⁶⁴ K Moore, B Haralambous, above n 61.

C Gastmans, K Milisen, above n 27.

⁶⁵ K Moore, B Haralambous, above n 61.

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⁶⁷ Australian Law Reform Commission, above n 3, p 143.

⁶⁸ K Carnell and R Paterson, above n 6, p 120.

implementation of organisational policies and medication reviews, with varying results.⁶⁹ Development of strategies to reduce or avoid restrictive practices might consider the institutional aspects of residential care that generate an environment and culture in which residents' ability to exercise autonomy is limited, as well as promoting evidence-based practice for management of the behavioural and psychological symptoms of dementia.⁷⁰

How prevalent is the use of restrictive practices in Australia?

There are currently no comprehensive national data on the use of restrictive practices in residential aged care facilities in Australia. Residential aged care service providers have not been required to record and report on the use of restraint or restrictive practices on residents, although the Australian Government's National Aged Care Quality Indicator Program will introduce reporting requirements relating to physical restraint from 1 July 2019. Varying definitions of restraint, discussed above, also impact upon the data about prevalence.

Some international studies indicate that the use of physical restraint practices can vary significantly between countries and between residential aged care facilities.⁷¹ There is a lack of available data demonstrating the prevalence of physical restraint in residential care in contemporary Australia.⁷² Some older research provides at least some indication. A series of studies published between 1997 and 1998 concerning physical restraint in residential care facilities in Western Australia, Queensland, Victoria and New South Wales, found that 15–26% of residents in participating care homes were being physically restrained at the time of

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D Godkin, J Onyskiv, 'A Systematic overview of interventions to reduce Physical Restraint Use in Long-Term Care Settings' (1999) 6 The Online Journal of Knowledge Synthesis for Nursing 6. R Muniz, S Gomez, D Curto, R Herandez, B Marco, P Garcia, J Thomas, J Olazaran, "Reducing physical restraints in nursing homes: a report from Maria Wolff and Sanitas' (2016) 17(7) Journal of the American Medical Directors Association 633.

S Johnson, J Ostasziewicz, B O'Connell, 'Moving beyond resistance to restraint minimisation: A case study of change management in aged care' (2009) 6(4) *Worldviews on Evidence Based Nursing* 210.

R Mohler, R Richter, S Kopke, G Meyer, 'Interventions for preventing and reducing the use of physical restraints in long-term geriatric care' (2011) 16 *Cochrane Library* 2.

J Westbury, P Gee, T Ling, D Brown, K Franks, I Bindoff, A Bindoff, G Peterson, 'RedUSe: reducing antipsychotic and benzodiazepine prescribing in residential aged care facilities' (2018) 9 *Medical Journal of Australia* 398.

J Thompson Coon, R Abbott, M Rogers, R Whear, S Pearson, I Lang, N Cartmell, K Stein, 'Interventions to Reduce Inappropriate Prescribing of Antipsychotic Medications in People with Dementia Resident in Care Homes: A Systematic Review' (2014) 15 *Journal of the American Medical Directors Association* 706.

⁷⁰ G J Andrews, E Peter, 'Moral Geographies of Restraint in Nursing Homes' (2006) 3(1) *Worldviews on Evidence Based Nursing* 2.

⁷¹ Z Feng, J P Hirdes, T F Smith, H Finne-Soveri, I Chi, J N Du Pasquier, R Gilgen, N Ikegami, V Mor, 'Use of physical restraints and antipsychotic medications in nursing homes—a cross-national study' (2009) 24(10) *International Journal of Geriatric Psychiatry* 1110.
A D Foebel, G Onder, H Finne-Soveri, A Lukas, M D Denkinger, A Carfi, D Vetrano, V Brandi, R Bernabei, R Liperoti, 'Physical restraint and antipsychotic medication use among nursing home residents with dementia' (2016) 17(2) *Journal of American Medical Directors Association* 184.

⁷² S O'Keefe, 'Physical restraints and nursing home residents: dying to be safe?' (2017) 46(4) *Age and Ageing* 536.

survey. 73 A study carried out in a high care facility in Western Australia in 2005 found that 40% of residents were restrained.74

A 2009 study in 44 residential aged care homes in Sydney found that about half of the residents were being prescribed psychotropic medications.⁷⁵ A more recent national Australian study of residents in residential aged care facilities found that nearly two-thirds were regularly taking psychotropic medication. ⁷⁶ A recent international study found that about one-third of people with dementia were prescribed antipsychotic medications.⁷⁷ A recent literature review of studies of Australian aged care facilities found that the proportion of residents prescribed antipsychotic medication ranged from 13 to 42%. 78 The Third Australian Atlas of Health Care Variation 2018 reported Pharmaceutical Benefits Scheme data indicating that the number of people over the age of 65 years being dispensed antipsychotic medications had fallen since 2013–14. However, there was no major change in the overall volume of antipsychotic medications dispensed and variation in dispensing had increased.79

While studies have provided evidence that antipsychotic medication for people with dementia should be reviewed regularly, and that medication may be successfully reduced or discontinued, there is evidence of long-term use of antipsychotics among patients living with dementia in residential aged care facilities.80

Several inquiries have heard concerns about the prevalence and inappropriate use of psychotropic medication in aged care. The Australian and New Zealand Society for Geriatric Medicine submitted to the Australian Law Reform Commission's enquiry on Equality, Capacity and Disability in Commonwealth Laws that restrictive practices are 'still pervasive' in residential aged care facilities, 'particularly in relation to chemical sedation and

⁷³ A Retsas, 'The use of physical restraints in Western Australian Nursing Homes' (1997) 14(3) Australian Journal of Advanced Nursing 33.

A Retsas, H Crabbe, 'Breaking Loose—the use of physical restraints in Nursing Homes in Queensland Australia' (1997) 4(4) Collegian Journal of the Royal College of Nursing Australia 14. A Retsas, 'Survey findings describing the use of physical restraints in nursing homes in Victoria, Australia' (1998) 35 International Journal of Nursing Studies 184.

A Retsas, H Crabbe, 'The use of physical restraints in nursing homes in New South Wales, Australia' (1998) 35(3) International Journal of Nursing Studies 177.

⁷⁴ J Timmins, 'Compliance with best practice: implementing the best available evidence in the use of physical restraint in residential aged care' (2008) 6 International Journal of Evidence Based Health Care 345.

⁷⁵ J Snowdon, D Galanos, D Vaswani, 'A 2009 survey of psychotropic medication use in Sydney nursing homes' (2011) 194(5) Medical Journal of Australia 270.

⁷⁶ J Westbury, P Gee, T Ling, A Kitsos, G Peterson, 'More action needed: Psychotropic prescribing in Australian residential aged care' (2019) 53(2) Australian and New Zealand Journal of Psychiatry

⁷⁷ J Kirkam, C Sherman, C Velkers, C Maxwell, S Gill, P Rochon, D Seitz, 'Antipsychotic use in Dementia: Is there are problem and are there solutions?' (2017) 62(3) The Canadian Journal of Psvchiatrv 170.

⁷⁸ K Westaway, J Sluggett, C Alderman, A Moffat, N Procter, E Roughead, 'The extent of antipsychotic use in Australian residential aged care facilities and interventions shown to be effective in reducing antipsychotic use: A literature review' (2018) Dementia 1.

⁷⁹ Australian Commission on Safety and Quality in Health Care and Australian Institute of Health and Welfare, The Third Australian Atlas of Health Care Variation, 2018, p 272.

⁸⁰ H Y Shin, S Gadzhanova, E E Roughead, M B Ward, L G Pont, 'The use of antipsychotics among people treated with medications for dementia in residential aged care facilities' (2016) 28(6) International Psychogeriatrics 977.

inappropriate use of drugs'. 81 The National Prescribing Service has also highlighted evidence of over use of psychotropic medication.82

How are restrictive practices in aged care regulated in Australia?

There is a 'patchwork' of federal, state and territory laws, plus non-statutory policies and guidance that are relevant to restrictive practices in a residential aged care context.83 These include the aged care regulatory framework and guidance, health and medication regulation and guidance, and legal frameworks relating to consent to care and treatment. Restrictive practices should also be considered in the context of Australia's human rights obligations.

Aged care regulatory framework and guidance

The Aged Care Act

The Aged Care Act 1997 (Cth) (the Act) is the principal legislation regulating aged care in Australia. Aged care providers that receive government funding are required to comply with responsibilities under the Act concerning accountability, user rights and quality of care principles. Residential aged care services must meet standards set out in Quality of Care Principles issued under the Act to be eligible for government funding.

Under the Act, responsibilities of approved providers include:

- provision of care consistent with residents' rights to live in a safe, secure and homelike environment, and to move freely both within and outside the residential care service without undue restriction;84
- systems to identify and ensure compliance with all relevant legislation, regulatory requirements, professional standards, and guidelines;85
- effective management of challenging behaviours;⁸⁶
- safe and correct management of medication.⁸⁷

There are inferences that may be drawn from these responsibilities of residential aged care providers under the Act. For example, residents might reasonably expect that they will not be subject to unnecessary restrictive practices. It might be inferred that providers will ensure that they have systems in place to identify and comply with laws concerning consent to care and treatment, medication administration and professional guidelines concerning the use of restraints.

⁸⁷ Ibid, item 2.7.

⁸¹ Australian Law Reform Commission, above n 3, p 143.

⁸² National Prescribing Service, 'Antipsychotic overuse in dementia—is there a problem?' (2013) Health News and Evidence.

⁸³ Australian Law Reform Commission, above n 3, p 144.

⁸⁴ Aged Care Act 1997, Schedule 1 User Rights Principles 2014, Charter of Care Recipients' Rights and Responsibilities—Residential Care part 1(g).

⁸⁵ Quality of Care Principles 2014, schedule 2, part 1, item 1.2.

⁸⁶ Ibid, item 2.13.

Guidance issued to assist accreditation assessors determine compliance with the standards includes guidance relating to these requirements. The guidelines indicate that effective management of challenging behaviour should comprise individualised assessment and care planning processes that include the resident and others who are able to inform strategies to meet the needs of the resident, with restraint only used as a last resort. The provider should be able to demonstrate that it has processes in place for administration of medication that are safe and consistent with legislation and professional guidelines, and that residents are satisfied with management of their medications. The provider should ensure regular evaluation and review of the resident's mediation needs and preferences with a pharmacist or medical officer.

The Australian Government's (non-statutory) guidance applicable to providers includes guidance concerning the use of restrictive practices⁹¹ and medication management⁹² in residential aged care facilities. The Australian Commission on Safety and Quality in Health Care has also produced guidance on preventing falls in residential aged care, which includes guidance on use of restraint.⁹³

Recent changes to regulation under the Act

The Australian Government has announced a number of changes to the regulation of aged care service providers under the Act that will come into effect from 1 July 2019.

A new single set of quality standards applicable across aged care service types, will replace existing standards. The new standards require providers to demonstrate, for example, each consumer is supported to exercise choice and independence;⁹⁴ a service environment that enables consumers to move freely indoors and outdoors;⁹⁵ ongoing assessment and planning with consumers;⁹⁶ and, where clinical care is provided, a clinical governance framework that includes minimising use of restraint.⁹⁷

To support compliance with the new standards, the Aged Care Quality and Safety Commission has published *Guidance and Resources for Providers to Support the Aged Care Quality Standards, 2019,* which includes guidance on demonstrating compliance with standards concerning minimisation of restraint. The provider is required to demonstrate that restrictive practices are only used when absolutely necessary, as a last resort and in accordance with professional guidance and best practice. Organisational systems should limit and monitor use of restraint.⁹⁸

The Quality of Care Amendment (Minimising the Use of Restraints) Principles 2019 will impose obligations on providers that include ensuring that an assessment is carried out by a

⁹¹ Department of Health and Ageing, above n 7.

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Aged Care Quality Agency, Results and processes guide, 2014.
Aged Care Quality and Safety Commission, Results and Processes Guide, 2019.

⁸⁹ Aged Care Quality and Safety Commission, *Results and Processes Guide*, 2019, pp 66–67.

⁹⁰ Ibid, p 47.

Department of Health and Ageing, Guiding Principles for Medication Management in Residential Aged Care Facilities, 2012.

Australian Commission on Safety and Quality in Health Care, *Preventing Falls and Harm from Falls in Older People: Best Practice Guidelines for Australian Residential Aged Care Facilities*, 2009.

⁹³ Australian Commission on Safety and Quality in Health Care, *Preventing Falls and Harm from Falls in Older People: Best Practice Guidelines for Australian Residential Aged Care Facilities*, 2009.

Aged Care Quality and Safety Commission, Guidance and Resources for Providers to support the Aged Care Quality Standards, 2019, p 4 (Standard 1(2)(b)).

⁹⁵ Ibid, pp 93, 99–101 (Standard 5(3)(b)(ii)).

⁹⁶ Ibid, pp 23–25 (Standard 2).

⁹⁷ Ibid, pp 132, 148 (Standard 8(3)(e)(ii)).

⁹⁸ Ibid, p 148.

health practitioner who has concluded that restraint is required and that the reasons for the restraint and any alternatives to restraint that have been used are documented in the resident's care and services plan. The provider must regularly monitor the resident for signs of distress or harm while the resident is subject to the restraint.

From 1 July 2019, it will be mandatory for residential aged care service providers to provide data on three quality indicators, including use of physical restraint, to the Department of Health. Resources have been developed to assist residential services to collect and report quality indicator data. The Government has announced that it intends to publish the data by the end of 2019, although the Government has not announced the form the data will be presented in.

Health practitioner regulation

Health professionals, including pharmacists, medical practitioners, nurse practitioners including registered and enrolled nurses, who may be employed by or providing services to residents in residential aged care, are subject to regulation under national, state and territory legislation, including with respect to medication management.

Each of the states and territories has implemented legislation that is consistent with the *Health Practitioner Regulations National Law Act 2009* (Qld) (national law) providing for regulation and accreditation of health practitioners, although there are differences in how the national law operates in each of the states and territories.

National boards are the principal regulatory bodies under the national law. There are 16 health professions within the national regulation and accreditation scheme, each regulated by a national board. The Australian Health Practitioner Regulation Agency (AHPRA) provides support to national boards and administers the national regulation and accreditation scheme under the national law. A Ministerial Council comprised of ministers from each state and territory government, and the Australian Government provides policy direction and oversight of the national scheme. ¹⁰⁰

Health practitioners must meet registration standards developed by national boards and approved by the Ministerial Council for registration. Programs of study that qualify practitioners for registration must be accredited by an accreditation authority and approved by the relevant national board. The programs of study cover prescribing of medicines.

Other than in New South Wales and Queensland where alternate processes apply¹⁰³, concerns about a registered health practitioner's performance or conduct can be raised with to Australian Health Practitioner Regulation Agency and will be considered by the relevant national board. The national law provides for voluntary notifications of concerns about practitioners, which can be made by any person¹⁰⁴, and imposes mandatory obligations on

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⁹⁹ Australian Government Department of Health, *Quality indicators in residential aged care*, 2019, https://agedcare.health.gov.au/ensuring-quality/quality-indicators-for-aged-care.

¹⁰⁰ COAG Health Council, *Guide to the National Registration and Accreditation Scheme for health professions*, 2018, pp 1–4.

¹⁰¹ Health Practitioner Regulation National Law Act 2009 (Qld) s 38.

¹⁰² COAG Health Council, *Guide to the National Registration and Accreditation Scheme for health professions*, 2018, p 16.

¹⁰³ In these co-regulatory jurisdictions, notifications are managed through the relevant health complaints entities.

See, for example, COAG Health Council, *Guide to the National Registration and Accreditation Scheme for health professions*, 2018.

¹⁰⁴ Health Practitioner Regulation National Law Act 2009 (Qld) s 145.

health practitioners, employers and education providers to report notifiable conduct. 105 The national law empowers national boards to take a range of regulatory actions. For instance. national boards may suspend or impose conditions on a practitioner's registration, caution the practitioner or accept an undertaking from the practitioner. 106 A national board may establish a panel to consider concerns regarding a health practitioner 107 and in some circumstances will be required to refer the matter to a relevant state or territory tribunal. 108

National boards develop codes and guidelines. 109 Accredited professional education providers and a range of other professional and industry associations also publish information and guidance for their members, as do government agencies. Professional guidance may not be strictly binding on health practitioners but may be referred to in administrative or legal proceedings concerning professional conduct.

In the aged care sector, personal care workers are not required to hold registration and are not subject to the national scheme. This represents approximately 70% of the total workforce providing direct care in residential aged care. 110 To address concerns about unregistered health care workers, including workers within aged care, state and territory governments agreed to implement a national code of conduct for unregistered workers. 111 The code of conduct regime, to the extent enacted in each state and territory, empowers state and territory health complaints entities to take action in respect of breaches of a code of conduct. 112 Although, there may be some ambiguity about the extent to which personal care workers provide health services that come within the ambit of the regime, health services may have a different meaning in each state or territory legislation. 113

Medicines regulation

Medicines regulation in Australia is performed by the Therapeutic Goods Administration. Medicines approved for sale in Australia are registered or listed on the Australian Register of Therapeutic Goods and scheduled in the Poisons Standard under the Therapeutic Goods Act 1989 (Cth). 114 Most psychotropic medicines will be classed as either schedule 4 prescription only medicines (e.g. antipsychotics, antidepressants, most benzodiazepines) or schedule 8—controlled drugs (e.g. alprazolam, a benzodiazepine, or opioid analgesics).

Registration with a national board recognises the qualification and scope of practice of health practitioners, which may include prescription, supply or administration of medicines. For instance, registered nurses in Australia are qualified to administer medicines to patients. 115

114 Therapeutic Goods Administration, *The Poisons Standard (the SUSMP)*, 2019, viewed 8 April 2019, https://www.tga.gov.au/publication/poisons-standard-susmp.

http://anf.org.au/documents/reports/Management of Medicines Guidelines 2013.pdf.

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¹⁰⁵ Ibid, ss 141–143.

¹⁰⁶ Ibid, ss 155, 178.

¹⁰⁷ Ibid, s 182.

¹⁰⁸ Ibid, ss 193–193B.

¹⁰⁹ Health *Practitioner Regulation National Law Act 2009* (Qld) s 39. COAG Health Council, Guide to the National Registration and Accreditation Scheme for health professions, 2018, p 13.

¹¹⁰ K Mavromaras, G Knight, L Isherwood, A Crettenden, J Flavel, T Karmel, M Moskos, L Smith, H Walton and Z Wei, 2016 National Aged Care Workforce Census and Survey-The Aged Care Workforce, 2016, p 13.

¹¹¹ COAG Health Council Communique, A National Code of Conduct for Health Care Workers, 2015.

¹¹² COAG Health Council, Final Report: A National Code of Conduct for health care workers, 2015, p

¹¹³ Ibid, pp 13, 24–25.

¹¹⁵ Australian Nursing & Midwifery Federation, *Management of Medicines in Aged Care*, 2013, viewed 5 April 2019,

The Nursing and Midwifery Board may endorse a registered nurse as a nurse practitioner able to prescribe medication, including antipsychotics. 116 The Nursing and Midwifery Board may endorse enrolled nurses to administer medicines if they have completed education on medication administration. 117 However, legal authority for prescription, supply and administration of medicines is governed by legislation in each state and territory, such as the Drugs, Poisons and Controlled Substances Act 1981 (Vic), which determines who can prescribe, supply or administer, which medicines, in which circumstances, in what manner and for what purposes. 118 This includes requirements relating to particular classes of medicines, such as certain schedule 4 and schedule 8 medicines. The states and territories are responsible for administration of legislation relating to the supply and administration of medicines, including regulatory controls. 119

The Australian Health Practitioner Regulation Agency regulatory framework does not apply to personal care workers and does not authorise personal care workers to administer medication. The Australian Nursing and Midwifery Foundation has said that as the administration of medicines is within the ordinary scope of practice of registered and enrolled nurses; personal care workers should only provide assistance to people who are able to self-administer medication. 120 However, under legislation in some jurisdictions, personal care workers with appropriate medication administration training may be allowed to administer medicines under the management or supervision of a registered nurse. 121

¹¹⁶ Department of Health, Eligible Nurse Practitioners Questions and Answers, 2014, viewed 5 April 2019, http://www.health.gov.au/internet/main/publishing.nsf/Content/midwives-nurse-pract-qanda-

Pharmaceutical Benefits Scheme, Risperidone 500mcg tablet PBS listing, viewed 5 April 2019, https://www.pbs.gov.au/medicine/item/1842v.

117 If an EN has not completed medication administration education a notation of 'Does not hold Board-approved qualification in administration of medicines' will be placed on their on their registration: Nursing and Midwifery Board of Australia, Fact sheet: Enrolled nurses and medicine administration, 2016, viewed 5 April 2019,

https://www.nursingmidwiferyboard.gov.au/documents/default.aspx?record=WD10%2f1737%5Bv8 %5D&dbid=AP&chksum=kGZLk7skelMKbw36%2bv3Arg%3d%3d.

¹¹⁸ Australian Medical Association, *Prescribing rules for doctors*, 2013, viewed 15 April 2019, https://ama.com.au/article/prescribing-rules-doctors; Poisons and Therapeutic Goods Act 1966 (NSW); Poisons and Therapeutic Goods Regulation 2008 (NSW); Drugs, Poisons and Controlled Substances Act 1981 (Vic); Drugs, Poisons and Controlled Substances Regulations 2017 (Vic); Health Act 1937 (QLD) Health (Drugs and Poisons) Regulation 1996 (Qld); Medicines and Poisons Act 2014 (WA); Medicines and Poisons Regulations 2016 (WA); Controlled substances Act 1984 (SA); Controlled substances (Poisons) Regulations 2011(SA); Poisons Act 1971 (Tas); Poisons Regulations 2018 (Tas); Medicines, Poisons and Therapeutic Goods Act 2008 (ACT); Medicines, Poisons and Therapeutic Goods Regulations 2008 (ACT); Medicines, Poisons and Therapeutic Goods Act 2012 (NT); Medicines, Poisons and Therapeutic Goods Regulations 2014 (NT).

¹¹⁹ For example, in Western Australia, the Medicines and Poisons Branch of the WA Department of Health is responsible for administration of the Medicines and Poisons Act 2014 (WA); https://ww2.health.wa.gov.au/Articles/N R/Pharmaceutical-Services-Branch, in New South Wales, the Chief Pharmacist Unit and the Pharmaceutical Regulatory Unit within the New South Wales Ministry of Health are responsible for administration of the Poisons and Therapeutic Goods Act 1966 (NSW): https://www.health.nsw.gov.au/pharmaceutical/Pages/about-us.aspx.

¹²⁰ Australian Nursing and Midwifery Federation, *Administration of medicines*, 2018, viewed 23 April 2019, http://anmf.org.au/documents/policies/PS Administration Medicine.pdf.

121 Victorian Government Department of Health, Aged care medication management: 2010 legislative changes, https://www2.health.vic.gov.au/public-health/drugs-and-poisons/medicationmanagement-in-aged-care/aged-care-medication-2010-changes; see Drugs, Poisons and Controlled Substances Act 1981 (Vic) s 36E; Poisons Regulations 2018 (Tas) r 133.

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Providers may implement policies concerning administration of medication by personal care workers employed in their facilities, which may vary from provider to provider, 122

The Australian Government subsidises the cost of prescription medicines to the Australian public through the Pharmaceutical Benefits Scheme under the National Health Act 1953 (Cth). Subsidies are also provided to veterans through the Repatriation Pharmaceutical Benefits Scheme (RPBS) under the Veteran's Entitlements Act 1986 (Cth).

Medicines that can be subsidised under the Pharmaceutical Benefits Scheme are listed in the National Health (listing of Pharmaceutical Benefits) Instrument 2012. Under the Pharmaceutical Benefits Scheme, most medicines are listed as 'unrestricted benefits', meaning that a benefit will be paid if the medicine is prescribed (and dispensed) for the Therapeutic Goods Administration (TGA) approved indication. Use of medications for indications other than as specified in the Therapeutic Goods Administration approved product information ('off-label') is common in several areas of medicine particularly where evidence is less readily attainable (for example, paediatrics) or when economic factors limit applications for approval. However, there are significant issues associated with off-label medication to which prescribers must give careful consideration. 123

Some medicines are listed as 'restricted benefits', meaning that a benefit will only be paid if the medicine is prescribed and dispensed for specific therapeutic uses. A subset of restricted benefits are 'authority benefits', which may be either:

- authority required (streamlined) benefits, meaning the prescriber must annotate the prescription with a code indicating for which indication the medicine is being prescribed; or
- authority required benefits, meaning the prescriber must seek the prior approval of the Department of Human Services to the prescription, having informed the Department of the indication.

The Practitioner Review Program analyses Medicare claims and Pharmaceutical Benefits Scheme prescribing data to identify servicing practices that differ from peers and which may indicate possible inappropriate practice. 124

Legal frameworks relating to consent to care and treatment

States and territories administer legal frameworks that provide for decision making with respect to care and treatment, which are relevant to care and treatment provided to people in residential aged care. The common law has recognised the importance of informed consent to treatment 125 and there may be legal consequences for providing care or treatment without lawful consent. 126 In the states and territories, various legislation provides a framework for

¹²² See, for example, Health Care Australia, Policy on Care Workers Assisting Residents with Medications in Residential Aged Care Facilities, 2012, viewed 23 April 2019, https://services.healthcareaustralia.com.au/education/HCA%20Policy%20Care%20Workers%20As sisting%20Residents%20with%20Medications%20GR%20081112.pdf.

¹²³ Council of Australian Therapeutic Advisory Groups, Guiding Principles for the quality use of offlabel medicines, 2013.

¹²⁴ See Department of Health, *Practitioner Review Program*, Canberra, 2018, viewed 26 April 2019, 'http://www.health.gov.au/internet/main/publishing.nsf/Content/practitioner-review-program.

¹²⁵ Rogers v Whitaker (1992) 175 CLR 479.

¹²⁶ Australian Law Reform Commission, Equality, Capacity and Disability in Commonwealth Laws, Report No 124, 2014, p 228.

determining when a person has impaired capacity affecting their ability to consent or make decisions about their care or medical treatment. The legislation provides for authorisation of substitute decision makers for people with impaired capacity.

The statutory frameworks allow people who have the capacity to make arrangements for their future care and medical treatment through the appointment of a substitute decision maker or advance care directive that will apply if the person does not have capacity to make a decision about care or treatment at the time a decision is required. 127

State and territory legislation determines who may provide lawful consent to medical treatment on behalf of a person with impaired capacity. For example, in New South Wales if a medical practitioner believes that a person has impaired capacity and is unable to make a decision concerning their care, they must seek consent from a person who is authorised to provide consent under the *Guardianship Act 1987* (NSW).

Civil and administrative tribunals in each of the states and territories have jurisdiction to determine matters concerning the health and welfare of adults with impaired capacity, including appointment of a substitute decision maker, such as a guardian. 129

The legislation variously sets out principles to be applied in authorisation of substitute decision makers and exercise of powers as a substitute decision maker. Some state and territory legislation includes express provisions concerning authorisation and use of restrictive practices. In South Australia, for example, the legal framework explicitly provides for a tribunal to determine where a person should live, detention in that place and use of force in providing care or treatment.¹³⁰

In the mental health setting, state and territory legislation provides for detention and administration of medication for mental disorder without patient consent. States and territories have also developed relevant policy guidance. There are number of statutory safeguards to protect the rights of people who receive treatment for mental illness under state and territory mental health legislation, including with respect to the use of restrictive practices.

¹²⁸ See, for example, Consent to Medical Treatment and Palliative Care Act 1995 (SA) Pt 2A; Guardianship and Administration Act 2000 (Qld) ss 11, 65, 66; Medical Treatment Planning and Decisions Act 2016 (Vic) ss 1, 4, 26, 50; Guardianship and Administration Act 1995 (Tas) ss 25, 39; Guardianship Act 1987 (NSW) ss 6E-F; Guardianship and Administration Act 1990 (WA) s 45, Pt 9D.

129 See, for example, Guardianship and Administration Act 1993 (SA) s 29; Guardianship and Administration Act 2000 (Qld) s 12; Guardianship and Administration Act 1986 (Vic) s 22; Guardianship of Adults Act 2016 (NT) s 11; Guardianship and Administration Act 1995 (Tas) s 20; Guardianship and Management of Property Act 1991 (ACT) s 7; Guardianship and Administration Act 1990 (WA) s 40; Guardianship Act 1987 (NSW) Pt 3.

See Guardianship and Administration Act 1993 (SA) s 32(1) under which the South Australian Civil and Administrative Tribunal is empowered to determine where a person should live including detention in that place and may authorise use of force in providing care and treatment.

¹³¹ See, for example, Disability Services Act 2006 (Qld); Mental Health Act 2016 (Qld); Disability Inclusion Act 2014 (NSW); Mental Health Act 2007 (NSW); Mental Health Act 2014 (Vic); Mental Health Act 2009 (SA).

¹³² See, for example, SA Health, *Restraint and Seclusion in Mental Health Services Policy Guideline*, 2015.

¹²⁷ See, for example, Medical Treatment Planning and Decisions Act 2016 (Vic) ss 26,50; Advance Care Directives Act 2013 (SA) s 23; Powers of Attorney Act 1998 (Qld) s 35; Advance Personal Planning Act 2013 (NT) s 8; Medical Treatment (Health Directions) Act 2006 (ACT) s 7; Guardianship Act 1987 (NSW) ss 6, 6G.

Some states and territories have legislation that explicitly regulates restrictive practices in disability services. The states and territories endorsed the *National Framework for Reducing and Eliminating the Use of Restrictive Practices in the Disability Service Sector* (National Framework) in March 2014, which was intended to inform the development of the National Disability Insurance Scheme (NDIS) quality assurance system and would provide a national approach to use of restrictive practices in disability services. The National Disability Insurance Scheme Commission will begin to regulate providers operating in Victoria, Queensland, Tasmania, Australian Capital Territory and Northern Territory from 1 July 2019 and Western Australia from 1 July 2020. The National Scheme Commission of the National Pramework for Reducing Insurance Scheme Commission will begin to regulate providers operating in Victoria, Queensland, Tasmania, Australian Capital Territory and Northern Territory from 1 July 2019 and Western Australia from 1 July 2020.

The use of terminology across the legislation, the legal basis for identifying a person has impaired capacity, appointment of substitute decision makers, the powers and duties of persons who may act as a substitute decision maker for a person with impaired capacity and the principles by which decisions are to be made, are not consistent. There is variation in the extent to which restrictive practices are explicitly regulated and safeguards that apply.

It has also been observed that statutory schemes that authorise care and treatment including restraint of people with impaired mental capacity without their informed consent apply in limited circumstances and the common law doctrine of necessity may not provide an adequate legal basis for restraint. 136

Australia's human rights obligations

Australia has agreed to be bound by human rights treaties that recognise and protect the human rights of all people equally, which include implicit obligations towards older people. The rights enshrined in the *International Covenant on Civil and Political Rights* include rights to self-determination¹³⁷, liberty and security of the person¹³⁸, recognition and equality before the law.¹³⁹ *The International Covenant on Economic, Social and Cultural Rights* protects the right to enjoyment of the highest attainable standards of physical and mental health.¹⁴⁰ The *Convention against Torture and Other Cruel, Inhuman or Degrading Treatment* (CAT) may also be relevant in the context of restraints in residential aged care.¹⁴¹

The Convention on the Rights of Persons with Disabilities clarifies the application of human rights to people with disabilities, including older people with physical or mental

139 Ibid, Art 16, 26.

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¹³³ See, for example, *Disability Act 2006* (Vic) Pt 7.

¹³⁴ Australian Law Reform Commission, above n 126, p 243.

¹³⁵ National Disability Insurance Agency, *Transition to the NDIS Quality and Safeguards Commission*, https://www.ndis.gov.au/providers/quality-and-safeguards.

¹³⁶ K Chandler, B White and L Wilmott, 'The doctrine of necessity and the detention and restraint of people with intellectual impairment: Is there any justification?' (2016) 23(3) *Psychiatry, Psychology and Law* 361.

¹³⁷ International Covenant on Civil and Political Rights Art 1(1).

¹³⁸ Ibid, Art 9(1).

¹⁴⁰ International Covenant on Economic, Social and Cultural Rights Art 12.

¹⁴¹ Australian Law Reform Commission, above n 126, p 39. Australia has ratified the Optional Protocol to the Convention against Torture and other Cruel, Inhuman and Degrading Treatment (OPCAT). The objective of the OPCAT is to establish a system of regular visits undertaken by independent international and national bodies to places where people are deprived of their liberty, in order to prevent torture and other cruel, inhuman or degrading treatment or punishment. A residential care home where people may not be free to leave could fall within the scope of a 'place of detention.'

impairments.¹⁴² The Convention reiterates the principle of personal autonomy.¹⁴³ In ratifying the Convention, Australia accepted obligations with respect to promoting mobility, independence¹⁴⁴ and the highest attainable standard of health for people with disabilities (including requiring free and informed consent).¹⁴⁵ Within the Convention, it is acknowledged that the existence of a disability does not justify a deprivation of liberty.¹⁴⁶ The right to equal recognition before the law, including support needed to exercise legal capacity, is enshrined within the convention.¹⁴⁷

While not enforceable unless incorporated into domestic law, human rights treaties are a statement of what Australia and the international community agree to be fundamental human rights. The treaties inform interpretation of existing laws and development of new legal frameworks. Where not already provided for in existing legislative or other arrangements, in signing the treaties the Australian Government has undertaken to take steps necessary to adopt legislative or other measures necessary to give effect to the recognised rights. 149

Previous enquiries and recommendations

Several enquiries and reviews have considered the issue of restrictive practices in residential aged care in Australia. Recent enquiries by the Australian Law Reform Commission, and Ms Kate Carnell and Professor Ron Paterson (Carnell and Paterson) concluded that legislative reform, including explicit regulation of restrictive practices in residential aged care in Australia, is needed. 150

The Australian Law Reform Commission highlighted the 'patchwork' of federal, state and territory laws and policies that apply to restrictive practices and has recommended development of a national approach to regulation of restrictive practices in aged care. ¹⁵¹ It recommended amendment of aged care legislation ¹⁵² and a review of state and territory laws concerning decision making, to provide a consistent decision making model and promote supported decision making in statutory decision making frameworks. ¹⁵³ Specifically, it recommended that: ¹⁵⁴. ¹⁵⁵

Restrictive practices in residential aged care

¹⁴² United Nations—Disability Department of Economic and Social Affairs, What is the Convention on the Rights of Persons with Disabilities?, www.un.org/development/desa/disabilities/convention-onthe-rights -of-persons-with-disabilities/frequently-asked questions-regarding-the-convention-on-therights-of-persons- with-disabilities.html.

¹⁴³ Convention on the Rights of Persons with Disabilities Art 3(1).

¹⁴⁴ Ibid, Art 20.

¹⁴⁵ Ibid, Art 25.

¹⁴⁶ Ibid, Art 14.

¹⁴⁷ Ibid, Art 12.

Australian Law Reform Commission, above n 126, p 28.
Minister for Immigration and Ethnic Affairs v Teoh (1995) 183 CLR 273, 286–8, 315.
See also Kioa v West (1985) 159 CLR 550.

¹⁴⁹ Convention on the Rights of Persons with Disabilities Art 4.
International Covenant on Civil and Political Rights Art 2.

Australian Law Reform Commission, above n 126, pp 248–49.
 Australian Law Reform Commission, above n 3, p 142.
 K Carnell and R Paterson, above n 6, p 119.

¹⁵¹ Australian Law Reform Commission, above n 126, p 248.

¹⁵² Ibid, p 170.

¹⁵³ Ibid, pp 21, 274.

¹⁵⁴ Ibid, p 21.

¹⁵⁵ Ibid.

The *Aged Care Act 1997* (Cth) should be amended to include provisions dealing with supporters and representatives consistent with the Commonwealth decision-making model [recommended by the ALRC].

. . .

State and territory governments should review laws and legal frameworks concerning individual decision-making to ensure they are consistent with the National Decision-Making Principles and the Commonwealth decision-making model. In conducting such a review, regard should also be given to:

- a. interaction with any supporter and representative schemes under Commonwealth legislation;
- b. consistency between jurisdictions, including in terminology;
- c. maximising cross-jurisdictional recognition of arrangements; and
- d. mechanisms for consistent and national data collection.

Any review should include, but not be limited to, laws with respect to guardianship and administration; consent to medical treatment; mental health; and disability services.

While aiming to discourage the use of restrictive practices, the Australian Law Reform Commission recommended legislative regulation of restrictive practices in residential care facilities include the following principles: 156

- · least restrictive option;
- as a last resort:
- where necessary to prevent serious physical harm;
- the extent necessary and proportionate to the risk of harm;
- with approval by a person authorised by statute;
- as documented in a person's support plan;
- when subject to regular review.

The Australian Law Reform Commission also recommended additional oversight mechanisms, including a senior practitioner to provide expert leadership and oversight of the use of restrictive practices in aged care and disability services, and mandatory reporting on the use of restrictive practices. ¹⁵⁷ It proposed development of a consistent national approach to the regulation or restrictive practices. ¹⁵⁸

Carnell and Paterson supported the principles recommended by the Australian Law Reform Commission as key elements for inclusion in standards limiting the use of restrictive practices in aged care. In addition, they recommended that:¹⁵⁹

- approved providers be required to record and report the use of restrictive practices in residential aged care to the Aged Care Quality and Safety Commission;
- accreditation assessments review the use of psychotropic agents;

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¹⁵⁶ Australian Law Reform Commission, above n 3, pp 142, 143.

¹⁵⁷ Ibid, pp 142, 146.

Australian Law Reform Commission, above n 126, p 256.Australian Law Reform Commission, above n 3, p 147.

¹⁵⁹ Ibid, p 126.

 a Chief Clinical Advisor approve the use of antipsychotic medications for aged care residents.

Carnell and Paterson also recommended that the Chief Clinical Advisor appointed to the Aged Care Quality and Safety Commission develop professional guidance to reduce the use of restrictive practices. 160

Both the Australian Law Reform Commission and Carnell and Paterson made observations as to the significance and gravity of the inappropriate use of restraints in recommending explicit regulation and suggested that governments and providers should aspire to eliminate restrictive practices.¹⁶¹

In 2017, the Victorian Institute of Forensic Medicine published a number of recommendations for prevention of injury-related deaths in residential aged care facilities. In the case of physical restraint, it made 15 recommendations. At the heart of those recommendations is the need for residential aged facilities to focus on and be supported in sustaining a personcentred care approach that respects the human rights of each person. Other recommendations include that: 163

- physical restraint only occur in extremely limited circumstances and should involve at least two health professionals with documented reasons for the use, duration of use, outcome of restraint and any adverse events;
- facilities have a physical restraint policy that promotes alternative approaches but mandates that if restraint is to be imposed, the limits of the restraint are documented;
- use of physical restraint mandate specialist review of the resident's care plan to as to identify a strategy to eliminate or reduce the need for restraint; and
- restraint be instituted and monitored by staff with formal training and demonstrated competency to intervene in such a way.

Conclusions

Restraint impacts the rights and dignity of older people in residential aged care. There is significant public interest in the issue of restraint and ways to reduce or avoid its use.

Some consider physically restricting a resident's movements, or administering medication that can have a restrictive effect on a resident, is justified in some circumstances when providing care or medical treatment. However, there is a body of evidence that identifies significant risks to older people associated with the use of both physical restraint and medications, such as psychotropic medications, that affect a resident's movement or ability to make decisions. Current professional standards and guidance applicable to residential aged care indicate alternatives to restraint should be attempted before restraint is used.

There is no reliable data that reveals the prevalence of the use of physical or chemical restraint. Some research suggests there is significant variability between residential care

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¹⁶⁰ Ibid, p 125.

¹⁶¹ Australian Law Reform Commission, above n 3, p 145.

J E Ibrahim, Recommendations for Prevention of Injury-Related Deaths in Residential Aged Care Services. Health Law and Ageing Research Unit, Department of Forensic Medicine Monash University, 2017, p 19.

¹⁶³ J E Ibrahim, Recommendations for Prevention of Injury-Related Deaths in Residential Aged Care Services. Health Law and Ageing Research Unit, Department of Forensic Medicine Monash University, 2017, p 20.

facilities in the extent to which physical restraint occurs. Studies have indicated rates of psychotropic use by residents in aged care are high but this may also vary significantly between residential aged care facilities. Inconsistencies in the definition of restraint contribute to uncertainty about the prevalence of restraint in residential aged care.

The regulation of care and treatment of residents in aged care facilities, including restrictive practices, occurs through state and territory as well as Commonwealth legislation. A patchwork of legal frameworks applies to approval and funding of residential aged care providers, regulation of health practitioners, prescription and administration of medication and decision-making processes concerning care and treatment of people with impaired capacity. Previous enquiries have concluded legislation concerning restrictive practices needs reform. The Australian Government has recently made amendments to legislative requirements concerning restraint that will apply to aged care providers. Further inquiry is required into the nature and extent of restraint occurring in residential aged care, how best to deliver person-centred care services to people residing in aged care facilities (including those who have impaired cognition such as those living with dementia), and the systems including legal frameworks required to ensure the safety and quality of residential care services.

Appendix

The medicines tables below provide examples of psychotropic medicines and other medicines of interest available in Australia. Information is provided on: the conditions that the medicine is approved to treat; whether the medicine is subsidised by the Australian Government through the Pharmaceutical Benefits Scheme (PBS); and PBS Section 85 prescription volumes for financial year 2017–18.

- Table 1: Antipsychotics
- · Table 2: Drugs to slow progression of Dementia
- Table 3: Benzodiazepines + other sedatives/hypnotics/anxiolytics
- Table 4: Opioid analgesics
- Table 5: Antidepressants
- Table 6: Miscellaneous items of interest

Types of PBS Benefits as described on the PBS online website (screenshots of PBS medicines that fall into each of these categories attached at the end of this document): 164

- **Unrestricted Benefits—**where the doctor can prescribe through the PBS without restrictions on therapeutic use.
- Restricted Benefits—where the doctor can prescribe through the PBS when satisfied that
 the patient's clinical condition matches the approved therapeutic uses, as determined by the
 Pharmaceutical Benefits Advisory Committee (PBAC).
- **Authority Required (STREAMLINED)**—where the doctor can prescribe through the PBS for specific conditions by providing a 4 digit streamlined authority code.
- Authority Required—where the doctor can prescribe through the PBS only if prior approval
 is obtained from the Department of Human Services or Department of Veterans Affairs.
 Some items require authority in writing to be obtained from the Department of Human
 Services.

To reflect this, the tables below have been coded with PBS Listing statuses:

U = Unrestricted	R = Restricted	A = Authority Required	AS = Authority Required (STREAMLINED)
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Medicines can be listed in more than one of the above PBS benefit categories. For example, Oxazepam is listed on the PBS as an unrestricted item for a single pack of 25 x 15mg tablets with no repeats. If a prescriber wants to write a prescription for Oxazepam 50 x 15mg tablets with 2 repeats, this will need to be written as an Authority prescription. Different formulations or strengths of a medicine may also have different PBS listing categories—e.g. Morphine tablets may have different PBS listing criteria compared to Morphine liquid in ampoules for injection.

All PBS indications are sourced from individual PBS medicine listings as of April 2019. All Therapeutic Goods Administration (TGA) indications are sourced from individual medicine summaries provided on the Australian Register of Therapeutic Goods as of April 2019. BBS listing indications and TGA treatment indications have sometimes been summarised for brevity. PBS 2017-18 prescription volumes have been generated using publicly available Section 85 date of supply data that was updated in April 2019. BBS prescription volumes include above and below co-payment prescriptions for all patient categories, including prescriber bag items. RPBS items are also included.

http://www.pbs.gov.au/info/general/faq#WhatareUnrestrictedRestrictedAndAuthorityRequiredItems.

165 Therapeutic Goods Administration, *Australian Register of Therapeutic Goods Search*, https://tga-

search.clients.funnelback.com/s/search.html?query=&collection=tga-artg.

Department of Health, Pharmaceutical Benefits Scheme Frequently Asked Questions—What are Unrestricted, Restricted and Authority Required Items,

Department of Health, *Pharmaceutical Benefits Scheme PBS and RPBS Section 85 Date of Supply Data*, http://www.pbs.gov.au/info/statistics/dos-and-dop/dos-and-dop.

Table 1: Antipsychotics

Medicine name	PBS Listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescription volume
Amisulpride	AS	Schizophrenia	Acute and chronic schizophrenic disorders	87,292
Aripiprazol e	AS	Schizophrenia	Schizophrenia including maintenance therapy Acute treatment of manic or mixed episodes associated with Bipolar I Disorder in adults Maintenance treatment of manic or mixed episodes in Bipolar I Disorder in adults	302,281
Asenapine	AS	Schizophrenia Acute mania or mixed episodes associated with bipolar I disorder Bipolar I	Schizophrenia in adults Treatment of acute manic or mixed episodes associated with Bipolar 1 Disorder Prevention of relapse of manic or mixed episodes in Bipolar 1 Disorder	25,394
Brexpipraz ole	AS	Schizophrenia	Treatment of schizophrenia	9,368
Chlorproma zine	U		Acute functional psychosis Long-term treatment of schizophrenia Short-term treatment of agitation and/or behavioural disturbance in patients with delirium or dementia Short-term treatment of agitation and severe depression Severe behavioural disturbances, as can be found in some children with mental retardation or autism Management of terminal illness to enhance the effect of analgesics and to control nausea and vomiting Control of intractable hiccough	71,282
Clozapine	AS * S100 Highly Speciali sed Drug	• Schizophrenia under the treatment of a psychiatrist or with the agreement of one when patient non-responsive or intolerant of other neuroleptic agents	Treatment-resistant schizophrenia, when non-responsive to, or intolerant of other antipsychotic drugs	Not available in Section 85 PBS data
Flupentixol	U		Maintenance treatment of chronic schizophrenia and other chronic psychoses, in patients intolerant of and/or refractory to other depot preparations; not for short-term use (less than 3 months)	13,825

Medicine name	PBS Listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescription volume
Haloperidol	U		Management of psychotic disorders Manic phase of manic depressive illness Gilles de la Tourette syndrome For the relief of delusions, hallucinations and confused states in acute alcoholism Treatment of intractable nausea and vomiting associated with radiation or malignancy	89,967
Lurasidone	AS	Schizophrenia	Treatment of schizophrenia in adults and adolescents (aged 13 to 17 years)	92,664
Olanzapine	AS	Schizophrenia Bipolar I	Treatment of schizophrenia and related psychoses Acute manic episodes associated with the short-term treatment of with Bipolar I Disorder Preventing recurrence of manic, mixed or depressive episodes in Bipolar I Disorder	1,088,930
Paliperidon e	AS	Schizophrenia	Acute and maintenance treatment of schizophrenia in adult patients	202,572
Periciazine	U		Severe anxiety and tension states and the maintenance treatment of the psychotic patient; useful in controlling such symptoms as impulsiveness and aggression	51,336
Quetiapine	AS	Schizophrenia Bipolar I Acute mania associated with bipolar I	Schizophrenia Bipolar disorder—maintenance and treatment of acute mania and depressive disorders Major depressive disorder Generalised anxiety disorder	1,081,129
Risperidon e	AS	Schizophrenia Acute mania in bipolar I Bipolar I Behavioural disturbances in patients with Alzheimer's type dementia who are unresponsive to non-pharmacologic al treatment for up to 12 weeks Severe behavioural disturbances in patients with autism	Schizophrenia and related psychoses Short term treatment of acute mania in Bipolar I disorder Bipolar I Psychotic symptoms, agitation or aggression unresponsive to non-pharmacological approaches in patients with moderate to severe Alzheimer type dementia (up to 12 weeks) Treatment of conduct and other disruptive behaviour disorders in children, adolescents and adults with sub-average intellectual functioning or mental retardation in whom destructive behavioural erreatment of behavioural disorders associated with autism in children and adolescents	591,841

Medicine name	PBS Listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescription volume
Ziprasidone	AS	Schizophrenia Acute mania or mixed episodes associated with bipolar I disorder	Treatment of schizophrenia, related psychoses, prevention of relapse and for maintenance of clinical improvement during continuation therapy Short term treatment of acute manic or mixed episodes associated with bipolar I disorder	32,165
Zuclopenthi xol	U		Treatment of acute psychoses, mania and exacerbation of chronic psychoses	38,157

^{*} PBS S100 Highly Specialised Drugs have PBS restrictions which apply to their prescribing and supply. 167

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Department of Health, Pharmaceutical Benefits Scheme Browse by Section 100 Item list: Section 100—items available under special arrangement, https://www.pbs.gov.au/browse/section100.

Table 2: Drugs to slow progression of Dementia

Medicine Name	Medication Class	PBS listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescriptio n volume
Donepezil	Anticholinester ase	AS	• Mild to Moderately Severe Alzheimer's Disease	Treatment of mild, moderate and severe Alzheimer's disease	380,529
Galantamine	Anticholinester ase	AS	Mild to Moderately Severe Alzheimer's Disease	Treatment of mild to moderately severe dementia of the Alzheimer type	79,325
Memantine	N-methyl-D-as partate antagonist	AS	• Moderately Severe Alzheimer's Disease as the sole PBS subsidised therapy	Treatment of the symptoms of moderately severe to severe Alzheimer's disease	49,037
Rivastigmine	Anticholinester ase	AS	• Mild to Moderately Severe Alzheimer's Disease	• Treatment of mild to moderately severe dementia of the Alzheimer's type	70,231

Table 3: Benzodiazepines + other sedatives/hypnotics/anxiolytics

Medicine Name	Medicin e class	PBS Listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescriptio n volume
Alprazolam	Benzodi azepine	А	Panic disorder where other treatments have failed or are inappropriate	 Short term treatment of anxiety, including anxious patients with depression Panic disorder 	114,857
Bromazep am	Benzodi azepine	A *RPBS only	Short term treatment of terminal disease where patient is receiving palliative care Short term treatment of refractory phobic or anxiety states	Symptomatic relief of tension, anxiety and agitation	538
Buspirone	Non-ben zodiazep ine anxiolytic	A *RPBS only	Short term treatment of anxiety	Not listed on the ARTG. Accessed through the Special Access Scheme	40
Clobazam	Benzodi azepine	Not PBS listed		AnxietyShort-term treatment of insomnia associated with anxietyEpilepsy	Not PBS listed
Clonazepa m	Benzodi azepine	U, R, A		 Most types of epilepsy in children In adults, all varieties of generalised epilepsy and partial epilepsy Intravenous use for status epilepticus 	55,716

Medicine Name	Medicin e class	PBS Listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescriptio n volume
Diazepam	Benzodi azepine	U, A		Short term treatment of anxiety Acute agitation, tremor, delirium and hallucinosis in alcohol withdrawal Reflex muscle spasm due to local trauma to muscles, bones and joints Spasticity due to upper motor neuron lesions such as cerebral palsy and paraplegia, as well as in athetosis and stiff-man syndrome Intravenous use for controlling status epilepticus and the spasms of tetanus	2,511,445
Flunitrazep am	Benzodi azepine	A *RPBS only	Short term treatment of terminal disease where patient is receiving palliative care. Short term treatment of refractory phobic or anxiety states	Severe cases of insomnia	1,584
Lorazepam	Benzodi azepine	Not PBS listed		Anxiety disorders Short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms Pre-surgical medication taken the night before surgery and/or 1–2 hours prior to the surgical procedure	Not PBS listed

Medicine Name	Medicin e class	PBS Listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescriptio n volume
Midazolam	Benzodi azepine	Prescriber 's Bag only ¹⁶⁸		Intravenously for conscious sedation prior to short surgical, diagnostic, therapeutic or endoscopic procedures Intravenously for induction of anaesthesia, preliminary to administration of other anaesthetic agents Intramuscularly for preoperative sedation and to impair memory of perioperative events Intravenous use for status epilepticus	4,917
Nitrazepa m	Benzodi azepine	U, A		• Insomnia	253,686
Oxazepam	Benzodi azepine	U, A		Management of anxiety disorders Short-term relief of the symptoms of anxiety including anxiety associated with depression Alcoholics with acute tremulousness, confusional state or anxiety associated with alcohol withdrawal	974,474
Temazepa m	Benzodi azepine	U, A		Adjunctive therapy for the short term management of insomnia in adults	2,012,139
Zolpidem	Non-ben zodiazep ine hypnotic	Not PBS listed		Short term treatment of insomnia in adults	Not PBS listed
Zopiclone	Non-ben zodiazep ine hypnotic	R *RPBS only	Short term treatment of insomnia	Short-term treatment of insomnia (two to four weeks).	23,583

^{*} RPBS = Repatriation item only available on the Repatriation PBS to those who have a valid Health card issued by the Department of Veterans Affairs. 169

Flunitrazepam and Alprazolam are Schedule 8 Controlled Drugs subject to additional state and territory legislative requirements when prescribing, dispensing and storing.

Department of Health, *Pharmaceutical Benefits Scheme: Repatriation PBS Explanatory Notes*, https://www.pbs.gov.au/info/browse/rpbs/rpbs-explanatorynotes

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¹⁶⁸ Department of Health, *Pharmaceutical Benefits Scheme Prescriber's Bag*, http://www.pbs.gov.au/browse/doctorsbag.

Table 4: Opioid analgesics

Medicine Name	PBS listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescription volume
Buprenorphine	R, A + S100 opiate dependence program	Restricted to treatment for chronic severe disabling pain unresponsive to non-opioid analgesics Authority required for treatment of chronic severe disabling pain when patient is receiving palliative care Treatment of opiate dependence under the S100 Opiate dependence program	 Management of moderate to severe pain Treatment of opiate dependence 	1,419,797 (S85 prescription volume only)
Codeine	U		Relief of unproductive, dry and intractable coughs associated with colds and flu	217,897
Codeine + Aspirin	U *RPBS only		Temporary relief of acute moderate pain, inflammation and fever	303
Codeine + Paracetamol	U, A		Temporary relief of moderate to severe pain and fever	3,819,756

Medicine Name	PBS listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescription volume
Fentanyl	R, A	 Restricted to treatment for chronic severe disabling pain unresponsive to non-opioid analgesics Authority required for treatment of breakthrough pain when patient is receiving palliative care and has cancer 	Management of chronic pain requiring opioid analgesia Management of breakthrough cancer pain in patients with malignancies who are already receiving and tolerant to opioid therapy Adjunct during general anaesthesia	507,008
Hydromorphone	U, R		Relief and treatment of moderate to severe pain, including chronic pain	166,411
Methadone	R, A + S100 opiate dependence program	Restricted to treatment for severe disabling pain unresponsive to non-opioid analgesics Authority required for chronic severe disabling pain in palliative care Treatment of opiate dependence under the S100 Opiate dependence program	Analgesic in conditions where morphine would make a reasonable alternative Treatment of opioid drug addictions as substitute or maintenance therapy under specialist supervision	87,385 (S85 prescription volume only)
Morphine	U, R, A	, 5	 Prolonged relief of chronic, moderate to severe pain Treatment of chronic severe cancer pain, including in terminal cancer patients Pre-operative medication and analgesic adjunct in general anaesthesia 	534,451

Medicine Name	PBS listed item?	PBS Indication(s) if medicine is	TGA indication(s)	PBS 2017- 18 prescription
		only available		volume
		as authority or restricted		
		prescription		
Oxycodone		Restricted to	Management of opioid	
		treatment for	responsive moderate to	
		severe disabling	severe pain	
	R	pain,		
	K	including		3,532,476
		chronic pain, unresponsive		
		to non-opioid		
		analgesics .		
Oxycodone + Naloxone		 Restricted to treatment for 	Management of moderate to severe pain with naloxone	
Naioxone		chronic	used for prophylaxis of opioid	
		severe	induced constipation	
	R	disabling	Symptomatic treatment of	2,245,258
		pain unresponsive	patients with severe to very severe idiopathic restless leg	
		to non-opioid	syndrome after failure of	
Tanankadal		analgesics	dopaminergic therapy	
Tapentadol		 Restricted to treatment for 	Management and relief of moderate to severe chronic	
		chronic	pain unresponsive to	
		severe	non-narcotic analgesia	
	R	disabling pain		737,020
		unresponsive		
		to non-opioid		
Tramadol		analgesicsRestricted to	Relief of moderate to severe	
Tramador		acute	pain	
		treatment of		
		short term pain		
		Restricted to		
		treatment of		
	R	pain, including		2,702,883
		chronic pain,		2,702,000
		where aspirin		
		and/or paracetamol		
		alone are		
		inappropriate		
		or have failed		

^{*} RPBS = Repatriation item only available on the Repatriation PBS to those who have a valid Health card issued by the Department of Veterans Affairs. 170

All opioid medicines are Schedule 8 Controlled drugs except for Tramadol, and Codeine in combination with paracetamol or aspirin.

¹⁷⁰ Ibid.

Table 5: Antidepressants

Medicine Name	PBS listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescription volume
Agomelatine	Not PBS Listed		Major depression	Not PBS listed
Amitriptyline	U		Major depressive disorders Nocturnal emesis where organic pathology excluded	2,269,130
Citalopram	U		Major depression	1,764,134
Clomipramine	R	 Cataplexy associated with narcolepsy Obsessive-compulsive disorder Phobic disorders in adults 	 Cataplexy associated with narcolepsy Obsessive-compulsive disorder Phobic disorders in adults Major depression 	81,061
Desvenlafaxine	R	Major depressive disorders	Major depression	2,231,557
Dosulepin/Dothiepin	U		Major depression	352,373
Doxepin	U		Major depression	195,867
Duloxetine	R	Major depressive disorders	 Major depression Diabetic peripheral neuropathic pain Generalised anxiety disorder 	1,674,480
Escitalopram	R	 Major depressive disorders Moderate to severe generalised anxiety disorder Moderate to severe social anxiety disorder 	 Major depression Generalised anxiety disorder Social anxiety disorder Obsessive compulsive disorder 	4,187,423
Fluoxetine	R	 Major depressive disorders Obsessive-compulsive disorder 	 Major depression Obsessive-compulsive disorder Premenstrual dysphoric disorder 	1,961,918
Fluvoxamine	R	Major depressive disordersObsessive-compulsive disorder	Major depression Obsessive-compulsive disorder	441,536
Imipramine	U		Major depression Nocturnal emesis provided organic causes have first been excluded	19,271
Mianserin	R	Severe depression	Major depression	41,632

Medicine Name	PBS listed item?	PBS Indication(s) if medicine is only available as authority or restricted prescription	TGA indication(s)	PBS 2017- 18 prescription volume
Mirtazapine	R	Major depressive disorders	Major depression including relapse prevention	2,525,915
Moclobemide	R	 Major depressive disorders 	Major depression	106,348
Nortriptyline	R	Major depression where other anti-depressant therapy has failed	Major depression	165,206
Paroxetine	R	 Major depressive disorders Obsessive-compulsive disorder Panic disorder 	 Major depression Obsessive-compulsive disorder Panic disorder Social anxiety disorder/social phobia Generalised anxiety disorder Post-traumatic stress disorder 	1,030,623
Phenelzine	R	Depression where all other anti-depressants have failed or are inappropriate	Major depression. Should rarely be the first antidepressant drug used.	6,790
Reboxetine	R	Major depressive disorders	Major depression	44,392
Sertraline	R	 Major depressive disorders Obsessive-compulsive disorder Panic disorder 	 Major depression Obsessive compulsive disorder Panic disorder Social anxiety disorder/social phobia Premenstrual dysphoric disorder 	4,104,221
Tranylcypromine	U		Major depression	17,511
Venlafaxine	R	Treatment of major depressive disorders	 Major depression Generalised anxiety disorder Social anxiety disorder Panic disorder 	3,036,319
Vortioxetine	Not PBS Listed		Major depressive disorders	Not PBS Listed

Table 6: Miscellaneous items of interest

Medicine Name	Medicine Class	PBS listed item?	PBS indication(s) if medicine is only available as authority or restricted prescription	TGA indication	PBS 2017-18 prescripti on volume
Pregabalin	Antiepilep tic	AS	Neuropathic pain refractory to treatment with other drugs	 Treatment of neuropathic pain in adults Indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation 	4,076,599

Examples of PBS Medicines in the unrestricted, restricted, authority required (STREAMLINED) and authority required categories

An unrestricted benefit:



Body System	NERVOUS SYSTEM > PSYCHOLEPTICS > ANXIOLYTICS						
▶ Note							
Code & Prescriber	Medicinal Product Pack (Name, form & strength and pack size)	Max qty packs	Max qty units	No. of repeats	DPMQ	Max Safety Net	General Patient Charge
3132W	OXAZEPAM oxazepam 15 mg tablet, 25 (PI, CMI)	1	25	0	\$12.75	\$13.98	\$18.51

A restricted benefit:



An Authority Required (STREAMLINED) benefit:

NERVOUS SYSTEM > PSYCHOLEPTICS > ANXIOLYTICS

RISPER	IDONE						
Source	General Schedule						
Body System	NERVOUS SYSTEM > PSYCHOLEPTICS > ANTIPSYCHOTICS						
* Caution							
+ Note							
• △ Authority I	Required (STREAMLINED)						
Code & Prescriber	Modicinal Product Pack (Name, form & strength and pack size)	Max qty packs	Max qty units	No. of repeats	DPMQ	Max Safety Not	Genera Patien Charge
1842Y	RISPERIDONE	3	60	2	\$18.48	\$19.71	\$24.24
(MP) (NP)	risperidone 500 microgram tablet, 20 (PL CMI)						

An Authority required benefit:

General Schedule

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Source

Body System

▶ ▲ Authority F	<mark>Required</mark>						
Code & Prescriber	Medicinal Product Pack (Name, form & strength and pack size)	Max qty packs	Max qty units	No. of repeats	DPMQ	Max Safety Net	General Patient Charge
3134Y	OXAZEPAM oxazepam 15 mg tablet, 25 (PI, CMI)	2	50	5	\$14.17	\$15.40	\$19.93