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Pharmaceutical drug misuse

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by

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SUMMARY

The misuse of pharmaceutical drugs is a major public health issue in Australia, as highlighted by parliamentary, government and coroner reports. The NSW Coroner's Court is currently examining this issue as part of an inquest into the unrelated opioid overdose deaths of six people in 2016. There are fears that Australia could be heading down the same path as the United States, where prescription drug misuse has been described as an epidemic.

Description of drugs

Pharmaceutical drugs may be prescribed drugs or over the counter drugs that may be bought without prescription. The two main types of pharmaceutical drugs that are misused are opioid analgesics, which are used for pain management, and benzodiazepines, which treat stress and anxiety, and help with sleep. Both opioid analgesics and benzodiazepines can be addictive. Furthermore, there is the potential for iatrogenic dependence, where a person develops a physical dependence to a drug after using it to treat a legitimate medical issue. **[2]**

Prescribing trends

One study reported that between 1992 and 2012, there was a 15-fold increase in opioid dispensing in Australia. Another study, which used a larger dataset of prescriptions and a different measure of dispensing, found that between 1990 and 2014 there was almost a four-fold increase in opioid dispensing in Australia. It noted that Australia ranked eighth out of 179 countries on 2011-2013 opioid consumption, substantially behind the US, Canada and Germany but almost twice that of the UK. A separate Australian study concluded that between 1992 and 2011 there was a 25% decrease in dispensing of benzodiazepines. **[3]**

Misuse and sources

Misuse: In the 2016 *National Drug Strategy Household Survey (NDSHS)*, 4.8% of Australians aged 14 and over (around 1 million people) reported that they had misused a pharmaceutical drug in the previous 12 months. Misuse was defined as use for non-medical purposes. Of this group, 26% misused pharmaceutical drugs daily or weekly. Between 2007 and 2013, there was an upward trend in the misuse of pharmaceutical drugs. **[4.1]**

Sources: According to the 2016 NDSHS, about half of those who had recently used opioid analgesics for non-medical purposes usually obtained them over-the-counter at a pharmacy. People who misused benzodiazepines (36%) were about twice as likely as those who misused opioid analgesics (18.2%) to usually obtain them with a medical prescription. Similarly, they were much more likely to obtain them via a friend, relative, or partner (41% compared with 20%). A systematic review of empirical studies published between 1996 and 2017 in Australia and overseas found that pharmaceutical drugs are primarily sourced for non-medical use from friends and family. **[4.2]**

Overdose deaths

In 2016, the Australian Bureau of Statistics reported that there were 1,808 drug induced deaths in Australia: the highest number since 1999. This included deaths

from legal and illegal drugs. The majority of drug induced deaths were due to accidental overdoses (71%), followed by suicidal overdoses (23%). Over half of all drug induced deaths had two or more substances identified on the toxicology report. Benzodiazepines were the most common drug type present, identified in 37% of deaths, followed by 'other opioids' (i.e. painkillers such as Oxycodone and Codeine), which were present in over 30% of deaths. Between 2006 and 2016, deaths involving benzodiazepines almost tripled (from 247 to 663) while deaths involving 'other opioids' more than doubled (from 242 to 550). **[5.1]**

The National Drug and Alcohol Research Centre reported 225 accidental opioid overdose deaths in NSW in 2013 (668 in Australia). Accidental overdose deaths from pharmaceutical opioids were 2.4 times higher than those from heroin. Between 2007 and 2013, there was a 68% rise in the number of accidental deaths due to opioids in both Australia and NSW. **[5.2]**

Legislation and guidelines

Commonwealth: Part 6-3 of the *Therapeutic Goods Act 1989 (Cth)* provides for the scheduling of substances, which allows restrictions to be placed on their supply to the public in the interests of public health and safety. Most opioids and some benzodiazepines are listed in Schedule 8 (Drugs of Addiction), with others listed in Schedule 4 (Prescription Only Medicines). In 2018, painkillers containing codeine that were available over-the-counter at pharmacies were rescheduled to Schedule 4, so that they now require a prescription. In January 2018 the Therapeutic Goods Administration released a consultation paper on regulatory options for dealing with the misuse of strong opioids in Australia. **[6.1]**

NSW: In NSW, medical practitioners must comply with the *Poisons and Therapeutic Goods Act 1966 (NSW)*. Part 3 of the Act regulates 'restricted substances', which means any substance in Schedule 4 of the Poisons Standard; and Part 4 regulates 'drugs of addiction', which means any substance in Schedule 8 of the Poisons Standard. A key provision in Part 4 of the Act is section 28, which prohibits a medical practitioner from prescribing drugs of addiction without a proper authority in certain circumstances. The maximum penalty for this offence is a $220 fine. In addition to criminal penalties, breach of legislative requirements may result in disciplinary action against medical practitioners. **[6.2]**

Professional guidelines: The Royal Australian College of General Practitioners has issued *Prescribing drugs of dependence in general practice* guidelines (updated October 2017) which covers the prescription of benzodiazepines and opioids. The Australian and New Zealand College of Anaesthetists has published *Recommendations regarding the use of Opioid Analgesics in patients with Chronic Non-Cancer Pain* (updated June 2015); and *Position statement on the use of slow-release opioid preparations in the treatment of acute pain* (April 2018). **[6.3]**

Government policy

National strategy: The *National Drug Strategy 2017-2026* applies to a range of drugs including the non-medical use of pharmaceutical drugs. As with previous versions of this Strategy, it outlines a national commitment to harm minimisation through balanced adoption of demand, supply and harm reduction strategies. The

Strategy notes that governments should consider the *National Pharmaceutical Drug Misuse Framework for Action 2012-2015*, which expired in 2015. **[7.1]**

Real time prescription monitoring: One priority of the 2012 Framework for Action was a new national electronic system for monitoring the prescription of Schedule 8 drugs. The proposed national system has not yet been implemented. In July 2017 the Commonwealth Minister for Health, Greg Hunt, announced that the Government would invest over $16 million for this national system. Tasmania is the only State to have a real-time prescription monitoring system. Victoria will begin rolling out its SafeScript system from late 2018. After an 18-month transitional period, it will be mandatory to check SafeScript prior to writing or dispensing a prescription for a high risk medicine. The ACT is also introducing a real time prescription monitoring system. **[7.3]**

NSW Government policy: The NSW Government has undertaken a range of actions to address pharmaceutical drug misuse including:

- programs to educate prescribers;
- monitoring supplies of Schedule 8 drugs to pharmacies;
- working towards a national prescription monitoring program;
- releasing a pain management strategy;
- considering the outcomes of take-home Naloxone trials; and
- increasing access to the Opioid Treatment Program. **[7.5]**

Policy recommendations

NSW Coroner: In June 2014, NSW Deputy Coroner Forbes made several recommendations, including that the NSW Health Minister consider steps that can be taken to implement a real time electronic prescription monitoring program within 12 months, and consider including all benzodiazepines within it. **[8.1]**

Victorian Parliamentary Committee: A March 2018 Victorian Parliamentary Committee report made several recommendations to the Victorian Government regarding pharmaceutical drug misuse. These included:

- Developing prescription opioid medication guidelines for GPs and training on prescribing practices;
- Developing resources and conducting awareness raising campaigns targeting the broader community;
- Resourcing the drug treatment sector to accommodate the likely influx of demand resulting from the new prescription monitoring system. **[8.2]**

United States policy responses

A 2011 national *Prescription Drug Abuse Prevention Plan* outlined action in four major pillars: (1) Education; (2) Tracking and monitoring; (3) Proper medication disposal; and (4) Enforcement. A 2016 report noted that the US had made substantial progress in implementing the plan. In relation to State Government policies, a 2016 article concluded that few rigorous evaluations had been conducted to examine the effects of these policies but that increasing evidence supported the effectiveness of several policies including expansion of drug take-back and Prescription Drug Monitoring Programs. **[9.1]**

1. INTRODUCTION

The misuse of pharmaceutical drugs is a major public health issue in Australia, as highlighted by parliamentary, government and coroner reports.[1] The NSW Coroner's Court is currently examining this issue as part of an inquest into the unrelated opioid overdose deaths of six people in 2016. At the start of the inquest, Counsel assisting the Coroner observed that "pharmaceutical opioid deaths in Australia now exceed heroin deaths by a significant margin – two to 2.5 times – the reverse of what was seen in the 1990s".[2] There are fears that Australia could be heading down the same path as the United States, where prescription drug misuse has been described as an epidemic.[3]

This paper examines the size of the problem in Australia. It then outlines the relevant Commonwealth and NSW legislation and professional guidelines for medical practitioners. Commonwealth and NSW government policy are also discussed, including the *National Pharmaceutical Drug Misuse Framework for Action 2012-2015.* In addition, policy recommendations from key Australian reports are canvassed. The final section reviews policy responses in the United States, including the 2011 *Prescription Drug Abuse Prevention Plan*.[4]

2. DESCRIPTION OF DRUGS

Pharmaceutical drugs "may be prescribed drugs – that is, where these drugs are formally prescribed by a doctor – or over the counter drugs that may be bought without prescription."[5] The two main types of pharmaceutical drugs that are misused are opioid analgesics, which are used for pain management, and benzodiazepines, which treat stress and anxiety, and help with sleep.[6]

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[1] See for example; State Coroner's Court of NSW, *Inquest into the deaths of Christopher Salib, Nathan Attard and Shamsad Akjtar*, Deputy State Coroner Forbes, 27 June 2014; Australian Institute of Health and Welfare, *Non-medical use of pharmaceuticals: trends, harms and treatment 2006–07 to 2015–16*, December 2017; Legislative Council of Victoria Law Reform, Road and Community Safety Committee, *Inquiry into drug law reform*, 27 March 2018.

[2] Thompson A, Six opioid deaths in the spotlight in coronial inquest, *Sydney Morning Herald,* 7 May 2018; McGowan M, 'He was gone': fentanyl and the opioid deaths destroying Australian families, *Guardian Australia,* 13 May 2018.

[3] See, for example, Power J, Prescription opioid epidemic coming to Australia, *Sydney Morning Herald,* 5 August 2017; Reddie M, Australia on brink of prescription painkiller epidemic, doctors say, *ABC News,* 13 May 2018.

[4] See also policy responses in Canada: Government of Canada, *Government of Canada Actions on Opioids: 2016 and 2017*, [website – accessed 16 May 2018].

[5] Ritter A, King T, Hamilton M, *Drug Use in Australian Society,* Oxford University Press, 2013, p 82,

[6] Australian Institute of Health and Welfare, *Non-medical use of pharmaceuticals: trends, harms and treatment 2006–07 to 2015–16*, December 2017, p 7-9.

Table 1: Commonly used opioid pharmaceuticals[7]

Pharmaceutical type	Common brand names	Description
Morphine	• MS Contin • Anamorph • Kapanol	Main component of opium, powerful narcotic analgesic
Codeine	• Panadeine Forte • Codral Forte • Mersyndol Forte	An extract of opium, which is not as strong as morphine
Buprenorphine	• Subutex • Suboxone • Temgesic	Used to treat pain and withdrawal from heroin, and in maintenance treatment to block the effects of other opioids
Oxycodone	• OxyContin • Endone	A semi-synthetic opioid analgesic similar to morphine
Methadone	-	Synthetic narcotic analgesic used in the treatment of opioid pain and dependence. Includes physeptone.

Table 2: Commonly used benzodiazepine pharmaceuticals[8]

Pharmaceutical type	Common brand names	Description
Alprazolam	• Xanax • Alprazolam • Tafil	Sedative commonly used to treat anxiety with symptoms of depression, and panic disorder
Clonazepam	• Rivotril • Paxam	Sedative used to treat epilepsy
Diazepam	• Valium • Ducene • Antenex	Anxiolytic and sedative that can be used to treat anxiety, muscle spasms, seizures, and alcohol withdrawal
Nitrazepam	• Mogadon • Aldodorm • Dormican	Hypnotic drug used for treatment of insomnia
Oxazepam	• Serepax • Miralaz	Sedative for treatment of anxiety with depression, and symptoms of alcohol withdrawal
Temazepam	• Normison • Temaze	Sedative used to treat insomnia

Both opioid analgesics and benzodiazepines can be addictive. Furthermore, there is the potential for *iatrogenic dependence,* where a person develops a physical dependence to a drug after using it to treat a legitimate medical issue.[9] A recent example from the media has been selected to illustrate this.

[7] Australian Institute of Health and Welfare, note 6, p 7

[8] Australian Institute of Health and Welfare, note 6, p 9

[9] Australian Institute of Health and Welfare, note 6, p 17.

Case example of iatrogenic dependence[10]

Joeleen, 24, is in the process of changing her lifestyle as she recovers from opioid addiction.

The keen photographer had been studying mental health but after the birth of her son a disc in her back prolapsed and she needed surgery.

She was prescribed painkillers Targin and Endone as part of her recovery but she simply never stopped taking them, and as the pain got worse, she took more.

Joeleen got to a stage where she was taking up to 20 pills a day.

"When I first took the Endone it felt really good, I felt really happy. I don't know how to describe it. It was kind of like a high feeling, kind of euphoric," she said.

"It just starts off as 'I'm in pain, I need painkillers', then you start getting used to the painkillers and you take more.

"It becomes your daily routine and you can't see yourself get through the day without them."

About six months ago Joeleen's friends and family began talking to her about her addiction.

"I used to say I wasn't addicted, I'm just dependent on them, but I was realising that I was panicking if I went out and didn't have any painkillers on me," she said.

"When I was weaning myself off the medication, it was really hard. I'd get migraines, get hot and cold flushes, sweats, I'd feel nauseous all the time.

"And the cravings. I always craved it. The pain was phenomenal, like the pain was so much worse than what I remembered before I was on the pain killers."

Joeleen recently had surgery on her arm and afterwards was prescribed Endone and Targin.

She's been taking it again for about a month.

"When you think of drugs and drug addiction, you think of illicit drugs, marijuana and cocaine. You don't really think of those you get from the doctor," she said

"All of a sudden you're addicted to these pain killers you got from a doctor. It's one of those sneaky ones that you don't see coming."

[10] Bonini T, Andersen B, and Evlin L, The opioid curse: Lives lost as patients addicted to painkillers prescribed dozens of drugs, *ABC Lateline,* 4 September 2017.

3. PRESCRIBING TRENDS

In recent decades, there has been a significant increase in the consumption of opioid pharmaceuticals in Australia. A 2014 journal article reported that:

> Between 1992 [and] 2012, there was a 15-fold increase in the number of PBS [Pharmaceutical Benefits Scheme]-listed opioid dispensing episodes (500 568 to 7 495 648). Oxycodone has been the main contributor to the increase in opioid utilization. The most striking recent trend has been the escalating use of buprenorphine and fentanyl for the treatment of pain.[11]

A 2016 study used a larger dataset of prescriptions (including estimates of non-PBS prescriptions) and a different measure of opioid dispensing, namely the number of defined daily doses per 1,000 population per day (DDD/1000 pop/day).[12] It found that between 1990 and 2014 there was almost a four-fold increase in opioid dispensing. The article further noted this trend in opioid usage:

> In 1990, weak, short-acting or orally administered opioids accounted for over 90% of utilization. Use of long-acting opioids increased over 17-fold between 1990 and 2000, due primarily to the subsidy of long-acting morphine and increased use of methadone for pain management. Between 2000 and 2011, oxycodone, fentanyl, buprenorphine, tramadol and hydromorphone use increased markedly. Use of strong opioids, long-acting and transdermal preparations also increased, largely following the subsidy of various opioids for non-cancer pain. In 2011, the most dispensed opioids were codeine (41.1% of total opioid use), oxycodone (19.7%) and tramadol (16.1%).[13]

The study also made some international comparisons:

> In 2011, we report dispensing of opioid analgesics at a rate of 18 DDD/1000 pop/day (17.4 DDD/1000 pop/day in 2014); this is somewhat lower than rates in Canada (22 DDD/1000 pop/day in 2010) and Scandinavia (approximately 20 DDD/1000 pop/day in 2006) who are among the leading consumers of opioid analgesics globally.
>
> A recent report by the International Narcotics Control Board (INCB) ranked Australia eighth out of 179 countries on 2011-2013 opioid consumption measured by DDDs for statistical purposes, substantially behind the US, Canada and Germany. However, levels of consumption in Australia were almost twice those in the UK.[14]

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[11] Blanch B, Pearson S and Haber P, An overview of the patterns of prescription opioid use, costs and related harms in Australia, *British Journal of Clinical Pharmacology,* 2014, 78(5), p 1161.

[12] Karanges E et al, Twenty-five years of prescription opioid use in Australia: a whole-of-population analysis using pharmaceutical claims, *British Journal of Clinical Pharmacology* 2016, 82(1), p 255-267.

[13] Karanges E et al, note 12, p 255. See also: Islam M et al Prescription opioid analgesics for pain management in Australia: 20 years of dispensing, *Internal Medicine Journal,* 2016, 46(8), p 955–963.

[14] Karanges E et al, note 12, p 262.

While the study suggested that the increase in opioid dispensing in Australia had been driven mainly by changes in subsidies for individual opioid analgesics, others have identified a range of other contributing factors, including:

> …a population that continues to grow rapidly in part because of increasing life expectancy with chronic illnesses of ageing often associated with pain, previous under-prescribing, increasing incidence and survival from cancer, increased numbers of preparations available, poor access to allied health for non-pharmacological interventions, poor undergraduate and postgraduate education about opioid prescribing, aggressive marketing and the imperative for health professionals to better manage pain.[15]

A 2016 article suggests that medical practitioners in Australia have been overprescribing opioid analgesics for chronic non-cancer pain (CNCP):

> [T]he use of opioids in the treatment of CNCP is controversial. While randomized-controlled trials have demonstrated efficacy of opioids for the short-term treatment of chronic pain, there is no high-quality evidence for their long-term efficacy. Despite this, treatment of CNCP accounts for almost 50% of opioid prescriptions written by Australian general practitioners…[16]

Studies have also examined trends in the dispensing of benzodiazepines in Australia. A 2014 study concluded that between 1992 and 2011 there was a 25% decrease in the number of DDD/1,000 pop/day.[17] It also found that "there were striking changes in use of individual benzodiazepines over time, with reductions in oxazepam and flunitrazepam and dramatic increases in alprazolam."

4. MISUSE AND SOURCES

4.1 Rates of misuse

The National Drug Strategy Household Survey reports on misuse of pharmaceutical drugs: 'misuse' is defined as:

> …use for non-medical purposes, which may include using medications in doses or frequencies other than prescribed to:
>
> • induce or enhance a drug experience
>
> • enhance performance
>
> • use for cosmetic purposes.[18]

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[15] Currow D, Phillips J and Clark K, Using opioids in general practice for chronic non-cancer pain: an overview of current evidence, *Medical Journal of Australia,* 204(8), p 307

[16] Karanges E et al, Twenty-five years of prescription opioid use in Australia: a whole-of-population analysis using pharmaceutical claims, *British Journal of Clinical Pharmacology* 2016, 82(1), p 262-263. See also Currow D, Phillips J and Clark K, note 15.

[17] Islam M et al, Twenty-year trends in benzodiazepine dispensing in the Australian population, *Internal Medicine Journal,* 2014, 44(1), p 57-64.

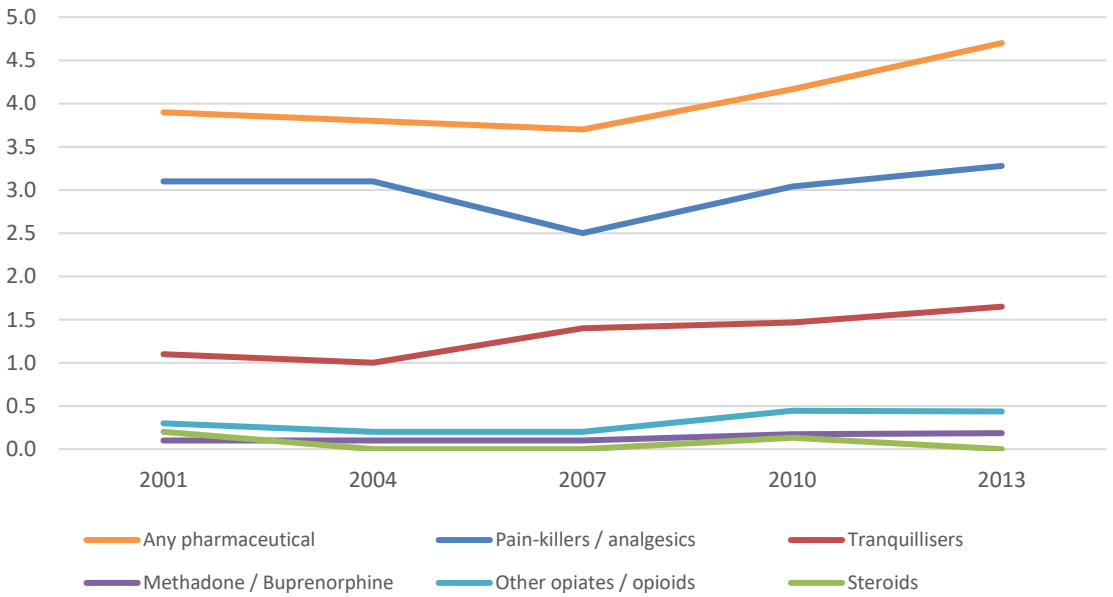
[18] Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2016*

In the 2016 survey, 4.8% of Australians aged 14 and over (around 1 million people) reported that they had misused a pharmaceutical drug in the previous 12 months. The most commonly misused pharmaceutical drugs were 'painkillers / analgesics & opioids' and 'tranquillisers'. A significant proportion (39%) of those who had misused a pharmaceutical drug in the previous 12 months had also used an *illicit* drug (e.g. marijuana, ecstasy, cocaine). Overall, 12.6% of Australians had used an *illicit* drug in the previous 12 months.[19]

Of those who misused a pharmaceutical drug in the previous 12 months, 26% did so daily or weekly, 17% did so about once a month, 24% did so every few months, and 33% did so once or twice a year.[20] People aged 20-29 and 40-49 were most likely to have misused pharmaceutical drugs in the previous 12 months (5.7% in both cases).[21] People aged over 50 were the most likely to have misused pharmaceutical drugs on a frequent basis (i.e. daily or weekly).[22]

Between 2007 and 2013, there was an upward trend in the misuse of pharmaceutical drugs (see Figure 1). Note that due to changes in the survey methodology, the 2016 results cannot be compared to previous years.[23]

Figure 1: Recent misuse of pharmaceuticals by type of drug, people aged 14 years or older 2001 to 2013[24]



Detailed findings, 2017, p 78-83.[19] AIHW, note 18, p 16.

[19] AIHW, note 18, p 16.

[20] Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2016 - Data Tables*, Table 6.5.

[21] AIHW, note 20, Table 6.3.

[22] AIHW, note 20, Table 6.6.

[23] AIHW, note 18, p 79-80.

[24] Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2013 -*

4.2 Sources for those who misuse

The 2016 National Drug Strategy Household Survey also provided information on the usual source of pharmaceutical drugs for those who had misused them in the previous 12 months:

> [A]bout half (52%) of those who had recently used opioid analgesics for non-medical purposes usually obtained them by purchasing over-the-counter pharmaceutical drugs at a pharmacy. About 1 in 6 (18.2%) usually obtained opioid analgesics with a medical prescription.
>
> People who used benzodiazepines (36%) were about twice as likely as those who used opioid analgesics (18.2%) to usually obtain them with a medical prescription. Similarly, they were much more likely to obtain them via a friend, relative, or partner (41% compared with 20%).
>
> A small proportion of people who recently used opioid analgesics (2.6%) and benzodiazepines (5.5%) for non-medical purposes acquired these pharmaceuticals from visiting multiple practitioners or pharmacies, but these results should be interpreted with caution due to the wide margin of error.
>
> Unsurprisingly, pharmaceuticals, such as opioid analgesics (2.4%) and benzodiazepines (5.5%), were far less likely to be acquired from a dealer than illicit drugs, such as meth/amphetamine (33%).[25]

A 2018 article reported the results of a systematic review and meta-analysis of the empirical research literature on the source and diversion of pharmaceutical drugs for non-medical use. The review of published research between 1996 and 2017 identified 149 studies published in Australia, Canada, Europe, the UK and the US; the meta-analysis related to 54 of these studies. In summary, it found:

> Pharmaceutical drugs are primarily sourced for [non-medical use] from friends and family (57%, 95% CI 53%–62%, I^2=98.5, n=30) and despite perceptions of healthcare professionals to the contrary, illegitimate practices such as doctor shopping are uncommon (7%, 95% CI 6%–10%, I^2=97.4, n=29). Those at risk of diversion include patients displaying aberrant medication behaviors, people with substance use issues and students in fraternity/sorority environments. Sourcing via dealers is also common (32%, 95% CI 23%–41%, I^2=99.8, n=25) and particularly so among people who use illicit drugs (47%, 95% CI 35%–60%, I^2=99.1, n=15). [26]

The study noted two factors that may contribute to the supply of pharmaceutical drugs between friends and family:

Data Tables, Table 6.2

[25] Australian Institute of Health and Welfare, *Non-medical use of pharmaceuticals: trends, harms and treatment 2006–07 to 2015–16*, December 2017, p 14.

[26] Hulme S, Bright D, and Nielsen S, The source and diversion of pharmaceutical drugs for non-medical use: A systematic review and meta-analysis, *Drug and Alcohol Dependence,* 2018, 186, p 242-256.

> First, few patients report receiving information from their treating practitioners about appropriate storage and disposal practices for leftover medications and consequently, patients regularly retain surplus medications that then become susceptible to misuse and diversion. Second, people may not be aware of the risks associated with diversion and NMU [non-medical use].[27]

An Australian study included in the meta-analysis involved a sample of 305 people entering drug treatment services in four States (Victoria, Western Australia, Queensland and Tasmania).[28] The eligibility of study participants was based on whether they reported regular and unsanctioned use of benzodiazepines and/or prescription opioids over the four weeks before treatment entry. The study found:

> Most benzodiazepine users (78%, n=113) reported a medical practitioner as a source of benzodiazepines in the 28 days before treatment entry. Most also reported a medical practitioner as their usual benzodiazepine source (72%, 88), and most reported acquiring benzodiazepines for real symptoms. Of those reporting non-medical sources as their usual supply, access through friends or acquaintances (buying, swapping or gifts) were most common; only 7% reported buying from a dealer as their usual source.[29]
>
> In contrast, about half of prescription opioid users (46%, 50) reported buying from a dealer. Most reported using non-prescribed sources (78%, 84), and most reported non-prescribed sources as their usual source (71%, 61).[30]

5. OVERDOSE DEATHS

5.1 Drug induced deaths

A 2017 Australian Bureau of Statistics (ABS) article reported on drug induced deaths in Australia between 1999 and 2016. The analysis included both legal and illicit drugs, accidental deaths and suicides. However, it cautioned that the 2016 data was preliminary and subject to a revisions process.[31]

In 2016, there were 1,808 drug induced deaths: the highest number since 1999 (1,740). The majority of drug induced deaths were due to accidental overdoses (71%), followed by suicidal overdoses (23%). Over half (59%) of all drug-induced deaths had two or more substances identified on the toxicology report. Benzodiazepines were the most common drug type present, identified in 37% of drug induced deaths (29% in 1999). The second most common drug type was 'other opioids' (i.e. painkillers such as Oxycodone and Codeine), which were present in over 30% of drug induced deaths (39% in 1999). The next most

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[27] Hulme S, Bright D and Nielsen S, note 26, p 251.

[28] Nielsen S et al, The sources of pharmaceuticals for problematic users of benzodiazepines and prescription opioids, *Medical Journal of Australia,* 2013, 199(10), p 696-699.

[29] Nielsen S et al, note 28, p 698.

[30] Nielsen S et al, note 28, p 698.

[31] ABS, *Drug Induced Deaths in Australia: A changing story,* 27 September 2017.

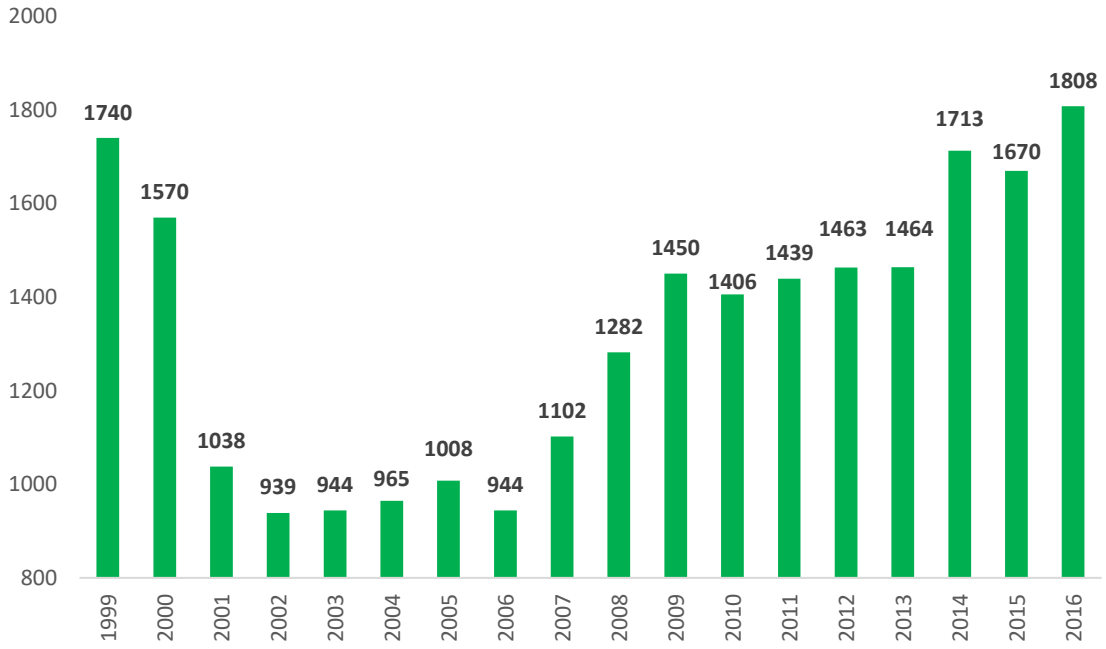
common were the illicit drugs meth/amphetamines and heroin: each were found in 20% of drug induced deaths, compared to 4% and 25% respectively in 1999.

Trends in drug induced deaths from 1999 to 2016, including by drug types, are shown in Figures 2 and 3. Since 2006, the number of drug induced deaths involving benzodiazepines has almost tripled (from 247 to 663); and the number of drug induced deaths involving 'other opioids' (which includes Oxycodone and Codeine) has more than doubled (from 242 to 550).

The ABS commented on the changing profile over time of drug induced deaths:

> In 2016, an individual dying from a drug induced death in Australia was most likely to be a middle aged male, living outside of a capital city who is misusing prescription drugs such as benzodiazepines or oxycodone in a polypharmacy (the use of multiple drugs) setting. The death was most likely to be an accident. This profile is quite different from that in 1999, where a person who died from a drug induced death was most likely to be younger (early 30s) with morphine, heroin or benzodiazepines detected on toxicology at death.[32]

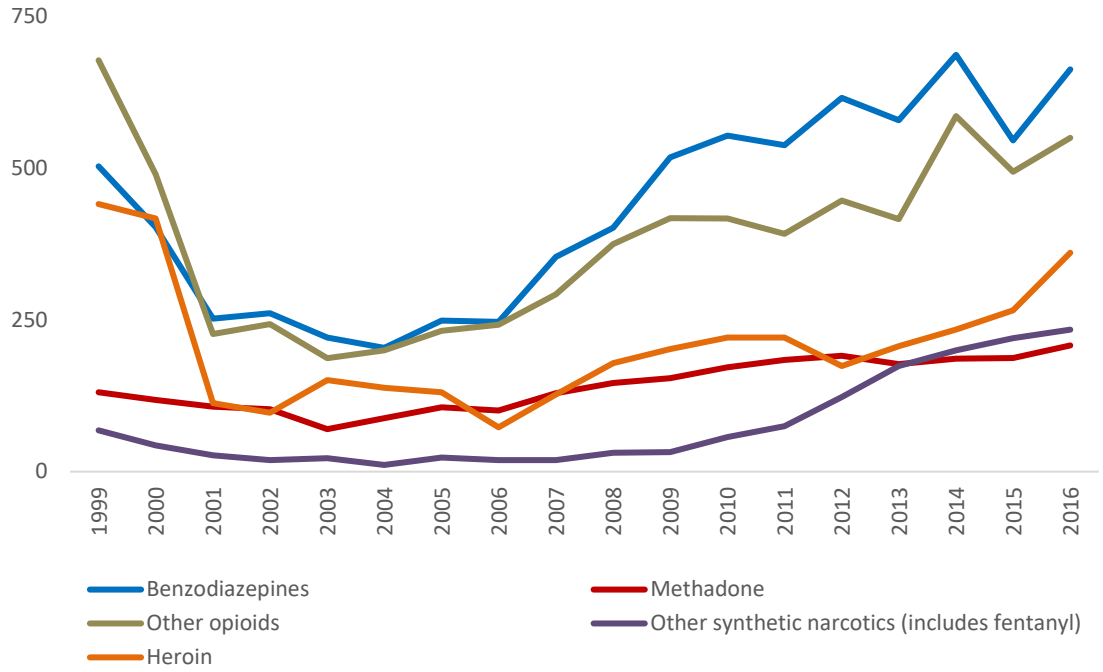
Figure 2: Drug induced deaths in Australia: 1999 to 2016[33]



[32] ABS, note 31.

[33] Australian Institute of Health and Welfare, *Non-medical use of pharmaceuticals: trends, harms and treatment 2006–07 to 2015–16 – Data Tables*, Table S16.

Figure 3: Drug induced deaths in Australia by drug type: 2001 to 2016[34]



5.2 Accidental opioid overdose deaths

A 2017 report by the National Drug and Alcohol Research Centre, which was based on ABS data, reported a total of 668 accidental opioid overdose deaths in Australia in 2013 (225 in NSW).[35] Of all accidental opioid overdose deaths, 470 (70%) were due to pharmaceutical opioids, and 198 (30%) were due to heroin. In other words, accidental deaths from pharmaceutical opioids were 2.4 times higher than those from heroin. Males comprised over two-thirds (70%) of accidental opioid overdose deaths. A media release accompanying the report stated:

> The opioid related deaths we are seeing today are showing very different patterns to what we saw at the peak of the heroin epidemic in the late 1990s and early 2000s.
>
> The vast majority of deaths involve prescription opioids rather than heroin, including strong painkillers such as oxycodone and fentanyl, and are among older Australians in their 30s, 40s and 50s.[36]

The report provided a time series from 2007 to 2013 on the number of accidental deaths due to opioids for persons of all ages in Australia and NSW (Figure 4);

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[34] AIHW, note 33, Table S16.

[35] Roxburgh A and Burns L, *Accidental drug-induced deaths due to opioids in Australia, 2013*, National Drug and Alcohol Research Centre, 2017.

[36] National Drug and Alcohol Research Centre, *More Australians dying of accidental overdose of pharmaceutical opioids*, Media Release, 24 July 2017.

and a longer time series – from 1988 to 2013 – on the number of accidental deaths in due to opioids among those aged 15-54 years in Australia and NSW (Figure 5). Between 2007 and 2013, there was a 68% rise in the number of accidental deaths due to opioids in both Australia and NSW. However, the number of accidental deaths in 2013 was well below the 1999 peak.

Figure 4 Number of accidental deaths due to opioids: persons of all ages, 2007-2013

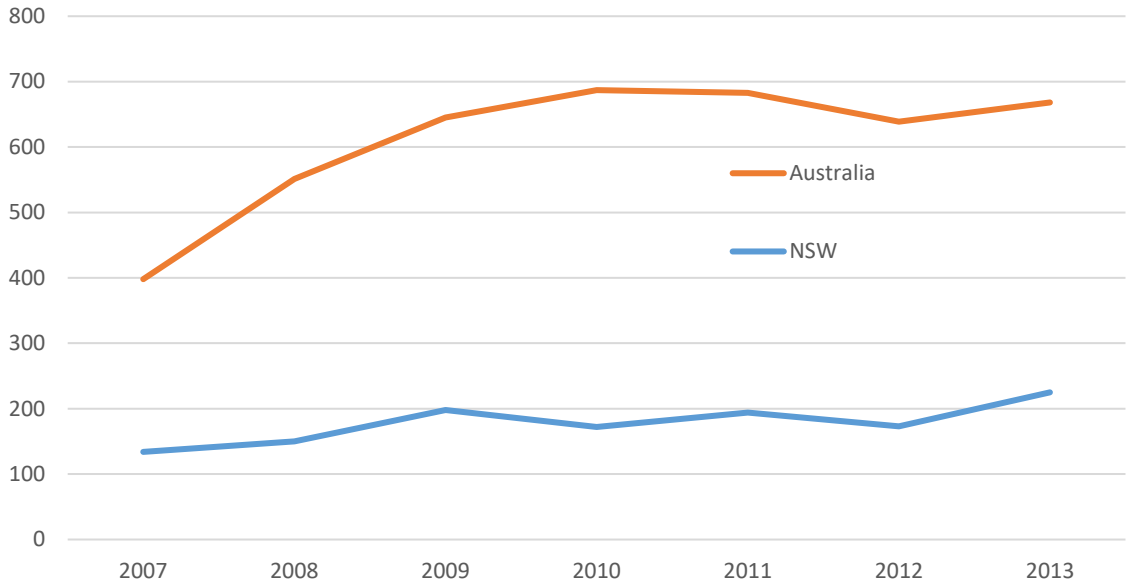
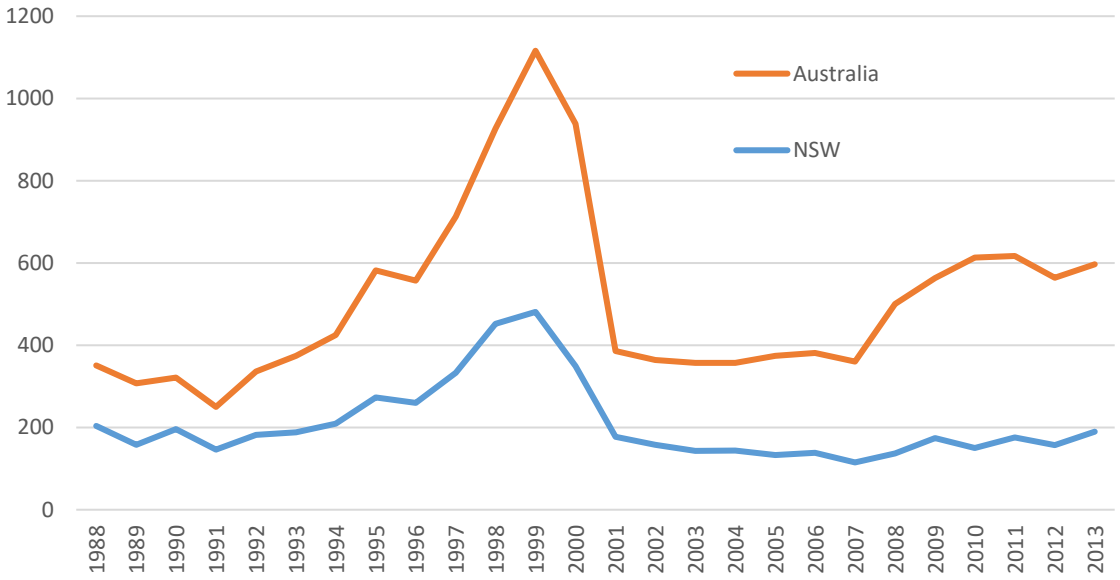


Figure 5 Number of accidental deaths due to opioids: persons aged 15-54, 1988-2013



Case example of accidental overdose death[37]

Heather was involved in a motor vehicle crash when she was 17 years old. She had many operations and was in a great deal of pain. Her doctors prescribed her significant levels of opioids for her pain in an era when the full difficulties of long-term, high dosage use of opioids were not fully appreciated. She became addicted.

Those high doses were ineffective in controlling her pain, and resulted in her losing functionality and mobility. She became obese, could no longer assist around the home and her family relationships became strained.

As the medical profession became more aware of the harm from opioids, her prescription levels were sought to be reduced. However, she maintained her dosage due to a number of factors, including receiving prescriptions from two doctors at the same time. This went undetected by her doctors and the Drug Management System overseen by the Northern Territory Department of Health.

She went into hospital in January 2015 for a total right hip replacement to try and solve some of her pain issues. She was prescribed even more opioids than before and was released on an increased dose that included 'take as required' opioids.

Her general practitioner was most concerned and sought clarification from the specialist about reducing the opioids. However, no reduction was made.

Heather died on 20 July 2015 of an unintentional overdose of her prescription medication. She was 43 years old.

6. LEGISLATION AND GUIDELINES

6.1 Commonwealth legislation

Part 6-3 of the *Therapeutic Goods Act 1989 (Cth)* provides for the scheduling of substances, which allows restrictions to be placed on their supply to the public in the interests of public health and safety. These schedules are published in a Commonwealth legislative instrument, the Poisons Standard, and are given legal effect through State and Territory legislation.

Most opioids and some benzodiazepines (Alprazolam and Flunitrazepam) are listed in Schedule 8 (Drugs of Addiction), with others listed in Schedule 4 (Prescription Only Medicines). In recent years, there have been some notable amendments to prevent the misuse of certain pharmaceutical drugs:

- In 2014, the benzodiazepine Alprazolam was rescheduled from Schedule 4 (Prescription Only Medicines) to Schedule 8 (Drugs of Addiction); and
- In 2018, commonly used painkillers containing the opioid codeine (e.g.

[37] Edited extract from NT Coroner's Court *Inquest into the death of Heather Fotiades* [2017] NTLC 012, 5 May 2017.

Panadeine, Nurofen Plus) were rescheduled from Schedule 3 (Pharmacist Only Medicine) to Schedule 4 (Prescription Only Medicines).[38]

In January 2018 the Therapeutic Goods Administration (TGA) released a consultation paper on regulatory options for dealing with the misuse of strong opioids in Australia.[39] The paper outlined eight options:

1. *Pack size changes:* make available for supply both smaller (such as maximum three-day) pack sizes for treatment of patients with acute pain and suitable pack sizes (14 or 28 days) for treatment of people with chronic pain due to malignancy.
2. *Reviewing the indications:* review the approved indications (i.e. the approved therapeutic use of a drug) for Schedule 8 opioids in the Australian Register of Therapeutic Goods and align them to current clinical guidelines for appropriate prescription of these products.
3. *Review registration of high dose products:* review whether higher dose Schedule 8 opioid products should continue to be registered; and consider if specific controls, such as approval to prescribe through States and Territories or the Pharmaceutical Benefits Scheme should be introduced.
4. *Strengthening risk management plans:* Review risk management plans for opioids to determine whether they currently reflect best practice in opioid prescribing and management of risks.
5. *Review label warnings:* warnings could be placed on the packaging of opioid products identifying the risk of dependence and overdose and lack of efficacy in the long term treatment of chronic non-cancer pain.
6. *Incentives for expedited review of improved products for pain relief:* provide priority review to new chemical entities that are viable alternatives to opioids for pain relief and also review of smaller pack sizes and/or abuse-deterrent formulations;
7. *Changes to use of appendices in Poisons Standard to provide additional regulatory controls:* Powers under medicines scheduling could include controls of prescribing for particular populations or classes of medical practitioners (e.g. specialist pain medicine physicians), additional safety directions or label warning statements, or specific dispensing labels.
8. *Increase health care professional awareness of alternatives to opioids:* Existing clinical guidelines for the management of pain provide advice on the use of non-pharmacological and alternate pharmacological therapies

[38] See NSW Health, Up-scheduling of alprazolam from Schedule 4 to Schedule 8 [website – accessed 5 March 2018]; Therapeutic Goods Administration, Codeine information hub, [website – accessed 15 February 2018]; and Hunter F, Formerly over-the-counter medicines containing codeine are now prescription only, *Sydney Morning Herald,* 30 January 2018.

[39] TGA, *Consultation: Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response*, 19 January 2018.

for pain management but there may be limited health practitioner awareness and uptake.

6.2 NSW legislation

In NSW, medical practitioners must comply with the *Poisons and Therapeutic Goods Act 1966 (NSW)*. Part 3 of the Act regulates 'restricted substances', which means any substance in Schedule 4 of the Poisons Standard; and Part 4 regulates 'drugs of addiction', which means any substance in Schedule 8 of the Poisons Standard.

A key provision in Part 4 of the Act is section 28, which prohibits a medical practitioner from prescribing drugs of addiction without a proper authority in certain circumstances. A proper authority is one issued by the Secretary of the NSW Ministry of Health. Section 28 states, in part:

(1) A medical practitioner or nurse practitioner must not, without the proper authority, prescribe for or supply to any person a type A drug of addiction.

(2) A medical practitioner or nurse practitioner must not, without the proper authority, prescribe or supply a type B drug of addiction:

a) for continuous therapeutic use by a person for a period exceeding 2 months, or

b) for a period that, together with any other period for which that drug or any other type B drug of addiction has been prescribed or supplied by the medical practitioner or nurse practitioner or has, to the medical practitioner's or nurse practitioner's knowledge, been prescribed or supplied by any other medical practitioner or nurse practitioner, would result in that drug, or that drug together with any other such drug, being prescribed or supplied for continuous therapeutic use for a period exceeding 2 months.

(3) A medical practitioner or nurse practitioner must not, without the proper authority, prescribe for or supply to a person who, in the opinion of the medical practitioner or nurse practitioner, is a drug dependent person a type C drug of addiction.

No opioids or benzodiazepines are prescribed as Type A drugs of addiction, although some are prescribed as Type B drugs of addiction. Type C drugs of addiction are all drugs of addiction other than a Type A drug of addiction.

Section 27 defines a drug dependent person as a person who has acquired, as a result of repeated administration of a drug of addiction or a prohibited drug, an overpowering desire for the continued administration of such a drug.[40]

Section 28 does not specify the maximum penalty for breaching the prohibition. However, section 44 provides that any offence for which no other penalty is expressly provided is liable to a penalty of two penalty units (currently $220).

[40] Section 27.

The *Poisons and Therapeutic Goods Regulation 2008 (NSW)* contains other requirements in relation to restricted substances and drugs of addiction. For example, clauses 34 and 79 stipulate that an authorised practitioner must not issue a prescription for these drugs in a quantity or for a purpose that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances. A breach of this clause carries a maximum penalty of a $2,200 fine, and/or six months' imprisonment.[41]

In addition to criminal penalties, breach of legislative requirements may result in disciplinary action against medical practitioners.[42] For example, in the 2016 case of *Health Care Complaints Commission v Tan*, a doctor who had over-prescribed drugs of addiction without an authority was found guilty of professional misconduct and had his registration cancelled.[43] The doctor's conduct included, over a long period of time, prescribing Oxycodone to a patient so far in excess of what is recommended for pain relief; prescribing Diazepam concurrently in circumstances that were potentially fatal; failing to heed advice from a pain specialist, failing to keep proper medical records; and being aware of the fact that he had no authority at law to prescribe the medication to the patient.

6.3 Professional guidelines

The Royal Australian College of General Practitioners has issued *Prescribing drugs of dependence in general practice* guidelines.[44] It has three sections:

- Part A – Clinical Governance Framework (published April 2015)
- Part B – Benzodiazepines (published July 2015)
- Part C – Opioid prescribing (published October 2017)

The introduction to the Clinical Governance Framework (Part A) states:

> Drugs of dependence have an important and valuable role in patient care. In recent years, the number of psychoactive drugs and formulations available in Australia has increased substantially. Many of these drugs have provided significant benefits to patients. However, the evidence demonstrates that pharmaceutical misuse is rapidly emerging as a drug problem.

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[41] For further information on the regulations, see NSW Health, *Guides for Medical Practitioners*, [website – accessed 5 March 2018]. For interstate comparisons of laws, see Jammal W and Gown G, Opioid prescribing pitfalls: medicolegal and regulatory issues, *Australian Prescriber*, 2015; 38, p 198-203; and Shand F et al, Real-time monitoring of Schedule 8 medicines in Australia: evaluation is essential, *Medical Journal of Australia,* 2013, 198(2), Appendix.

[42] See Mendelson D, Disciplinary proceedings for inappropriate prescription of opioid medications by medical practitioners in Australia (2010-2014) *Journal of Law and Medicine*, 2014, 22(2), p 255-279.

[43] [2016] NSWCATOD 77.

[44] Royal Australian College of General Practitioners, *Prescribing drugs of dependence in general practice*, 2017.

As one example of the Opioid prescribing guidelines (Part C), the following advice is provided on the use of opioids to manage chronic non-cancer pain (CNCP):

> For accountable prescribing in managing CNCP, GPs should:
>
> - undertake a complete biopsychosocial assessment of the patient with pain
> - optimise non-drug therapies, and optimise non-opioid therapies as the primary interventions of care.
>
> Opioids for CNCP should be reserved for selected patients with moderate or severe pain that has not responded to other therapies and that significantly affects function or quality of life. If primary interventions fail or are suboptimal, opioid therapies may be considered. GPs should share the decision-making process with the patient, and if opioid therapy is considered, there should be:
>
> - a patient selection/exclusion process before a therapeutic opioid trial
> - formal care planning based on specific goals and risks
> - an opioid trial, which is undertaken to determine a patient's response to opioid therapy. This trial includes the selection of an appropriate opioid, formal measures of analgesia and functionality, a trial of dose reduction, and a drug cessation plan if the trial fails
> - an ongoing assessment and evaluation by the accountable prescriber if the trial shows opioid benefit
> - opioid tapering and cessation if suboptimal results or aberrant behaviour occurs.
>
> Long-term use should be uncommon, undertaken with caution and based on consideration of the likely risks and benefits of opioids. Intermittent use is preferable.[45]

Other professional guidelines relevant to the prescription of opioids include:

- NSW Therapeutic Advisory Group, *Preventing and managing problems with opioid prescribing for chronic non-cancer pain*, July 2015;
- Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists;
    - *Recommendations regarding the use of Opioid Analgesics in patients with Chronic Non-Cancer Pain*, 2015; and
    - *Position statement on the use of slow-release opioid preparations in the treatment of acute pain*, 2018.

In an April 2018 media release, the Australian and New Zealand College of Anaesthetists said that it had written to 34 of Australia and New Zealand's leading medical colleges warning them about the potentially fatal risks of prescribing

[45] Royal Australian College of General Practitioners, *Prescribing drugs of dependence in general practice, Part C2 The role of opioids in pain management*, 2017.

slow-release opioids for relief of acute pain. It noted:

> Those at high risk from slow-release opioids include patients on benzodiazepines, some antihistamines, anti-depressant or anti-psychotic medication and patients with obesity and/or chronic sleep apnoea because the treatment can suppress their breathing, sometimes with fatal consequences. [46]

7. GOVERNMENT POLICY

7.1 National strategies

The *National Drug Strategy 2017-2026* applies to a range of drugs including the non-medical use of pharmaceutical drugs. As with previous versions of this Strategy, it outlines a national commitment to harm minimisation through balanced adoption of demand, supply and harm reduction strategies. The Strategy refers to several sub-strategies and notes that governments should also consider the *National Pharmaceutical Drug Misuse Framework for Action 2012-2015*, which expired in 2015. The Framework, which was informed by a literature review,[47] had nine priority areas (Table 3).

Table 3: Nine Priority Areas in the Framework for Action

Pharmaceutical type	Description
1. Coordinated medication management system	A coordinated medication management system is an on line, real - time tool that provides information on patients' relevant medication usage for prescribers, pharmacists and regulators. It is important that such a system be linked to the regulatory and monitoring approaches outlined in Priority Area 4.
2. Supporting prescribers	This area focuses on a range of strategies that enhance prescribing practice to minimise intentional and unintentional misuse. This includes the development of prescribing guidelines and workforce development measures.
3. Supporting pharmacists and other health professionals	This includes actions to enhance the role of pharmacists in medication management, as well as a range of practice enhancement measures for this group. It also highlights the need for other health professionals to be more aware of and involved in the appropriate treatment options for conditions such as pain, anxiety and sleep disorders.
4. Regulation and monitoring	This includes a range of enhancements to, and standardisation of, the ways medications are regulated and monitored and the ways in which data about pharmaceutical drugs are shared. The approaches outlined in this Priority Area should have close links to the coordinated medication management system (Priority Area 1).

[46] Australian and New Zealand College of Anaesthetists, *Prescribing slow-release opioids can be fatal, leading college warns*, Media Release, 4 April 2018

[47] Nicholas R, Lee N, Roche A, *Pharmaceutical drug misuse problems in Australia: Complex issues, balanced responses*, National Centre for Education and Training on Addiction, Flinders University, 2011.

Pharmaceutical type	Description
5. Structural factors	This area addresses a range of issues related to access to services, medication management and prescriber remuneration which may contribute to pharmaceutical drug misuse.
6. Health information and other consumer responses	This area addresses a range of health literacy issues including problems related to the acceptability of non-pharmacological treatments, the accessibility of information, medication labelling and the protection of patients' rights.
7. Treatment and harm reduction	This area focuses on the treatment needs of people with pharmaceutical drug misuse problems, and the access that Australians have to the resources they need to reduce the harms associated with pharmaceutical drug misuse.
8. Technological responses	This area seeks to implement measures such as tamper-resistant medications, pharmaceutical tracking measures and electronic prescribing to reduce pharmaceutical drug misuse.
9. Data, research and evaluation	This area contains strategies to enhance our understanding of the extent and nature of pharmaceutical drug misuse in Australia and appropriate responses.

No progress reports or evaluations of this Framework for Action have been published. Accordingly, it is unclear whether the actions supporting the identified priority areas have been completed.

7.2 Commonwealth Prescription Shopping Program

In 2005, the Commonwealth Government introduced the *Prescription Shopping Program* (PSP).[48] It has two parts. First, there is an 'Information Service', which is a telephone hotline that doctors can contact to find out if patients have been supplied with excess Pharmaceutical Benefit Scheme (PBS) medicines. The program does not cover medicines that are not subsidised under the PBS. Patients are considered to have been supplied with excess PBS medicines within a three month period if they meet any of the following criteria:

1) They were supplied with pharmaceutical benefits prescribed by 6 or more different prescribers; or
2) They were supplied with a total of 25 or more target pharmaceutical benefits; or
3) They were supplied with a total of 50 or more pharmaceutical benefits.

According to the Government's website, the information provided to doctors is accurate up to the last 24 hours.[49]

[48] Abbott T and Hockey J, *More help for GPs: new prescription shopping hotline opens*, Media Release, 11 February 2005. See also Australian Department of Human Services, *Prescription Shopping Program*, [website – accessed 5 March 2018].

[49] Australian Department of Human Services, note 48.

The second part of the program is an 'Alert Service':

> The alert service assesses patients monthly who meet the PSP criteria. We will write to patients and their prescribers if there are concerns the patient may be getting more PBS medicines than medically needed.[50]

A recent media report noted:

> The number of prescription drug abuse alerts in Australia rose by 26 per cent in 2017, with the Federal Government writing to 11,614 patients and doctors with concerns over patients who were prescription shopping.[51]

7.3 Real-time prescription monitoring system

A national system: Priority No 1 of the 2012 Framework for Action (a coordinated medication management system), proposed a new national electronic system for monitoring Schedule 8 drugs. It stated:

> Under the Commonwealth Fifth Community Pharmacy Agreement, the Australian Government announced on 12 February 2012 the establishment of a new national real time, on line coordinated Schedule 8 medication management system called the Electronic Recording and Reporting of Controlled Drugs (ERRCD) system.
>
> The ERRCD system is based on the Drugs and Poisons Information System Online Remote Access (DORA) system implemented in Tasmania which has had a positive impact on prescribers and dispensers as a result of the improved information available to them to assist their decision-making.[52]

The proposed national system has not yet been implemented. In July 2017 the Commonwealth Minister for Health, Greg Hunt, announced that the Government would invest over $16 million for this national system. The Health Minister said that the system would "provide an instant alert to pharmacists and doctors if patients received multiple supplies of prescription-only medicines".[53]

At a Council of Australian Government Health Council meeting in April 2018:

> The Ministers agreed to progress national real time prescription monitoring as a federated model with jurisdictions committed to progressing development and adaptation of systems to connect to and interface with Commonwealth systems to achieve a national solution.[54]

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[50] Australian Department of Human Services, note 48.

[51] Puddy R, Prescription abuse alerts spike, prompting urgent calls for national drug monitoring system, *ABC News,* 9 May 2018.

[52] *National Pharmaceutical Drug Misuse Framework for Action 2012-2015*, 2012, p17.

[53] Hunt G, *National approach to prescription drug misuse*, Media Release, 28 July 2017.

[54] COAG Health Council, *COAG Health Council Communique*, 13 April 2018.

State systems: Tasmania is the only State to have a real-time prescription monitoring system.[55] It was introduced in 2012.

The Victorian Government's 2016-17 State Budget included a $29.5 million commitment to introduce a real-time prescription monitoring system, SafeScript.[56] In 2017, the Victorian Parliament passed the *Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Bill 2017*. The SafeScript system is expected to start rolling out across Victoria from late 2018.[57]

After an 18-month period to allow health practitioners to familiarise themselves with Safescript, it will be mandatory to check SafeScript prior to writing or dispensing a prescription for a high risk medicine.[58] These include:

> …all Schedule 8 medicines…and some Schedule 4 medicines including all benzodiazepines such as diazepam, 'Z-drugs' such as zolpidem, and quetiapine. Codeine will be included at a later stage to allow clinicians time to adjust to the rescheduling of over-the-counter codeine products to prescription only. [59]

On 10 May 2018, the ACT Government introduced a bill to establish a real time prescription monitoring system. [60] This will be a voluntary system, meaning that doctors and pharmacists will not be required to use the system prior to prescribing or dispensing. However, the Government intends to consult with stakeholders about whether a mandatory system could be implemented once there is a nationally compatible scheme.[61]

Issues: In a 2013 article, Shand and others identified the potential benefits and unintended consequences from the introduction in Australia of real-time reporting systems for Schedule 8 medicines:

> **Potential benefits**
>
> - Reduction of inappropriate prescribing, overservicing and medication costs
> - Promotion of a more patient-centred approach to quality use of opioids
> - Reduction in prescription shopping and unsanctioned use, including diversion to illicit markets
> - Reduction in adverse events (including mortality, cognitive dysfunction,

[55] Department of Health and Human Services, *DORA - Drugs and Poisons Information System Online Remote Access*, [website – accessed 18 May 2018].

[56] Hennessy J and Foley M, *Real Time Prescription Monitoring Will Save Lives*, Media Release, 25 April 2016.

[57] Victorian Government, Safescript [website – accessed 5 March 2018].

[58] Victorian Government, note 57.

[59] Victorian Government, note 57.

[60] Medicines, Poisons and Therapeutic Goods Amendment Bill 2018. See also Burdon D, Delayed ACT prescription drug monitoring bill introduced, *Canberra Times,* 10 May 2018

[61] M Fitzharris, *ACT Hansard,* 10 May 2018.

accidents and incident dependence)

- Increase in multimodal pain management and less reliance on opioid analgesic-only approaches

Potential unintended consequences

- Overly cautious prescribing of Schedule 8 drugs, and possibly other drugs, when they are clinically indicated
- Some prescribers and patients might shift to Schedule 4 drugs to avoid scrutiny
- Unsanctioned users may shift to illicit drugs or other prescription drugs (eg, benzodiazepines, antipsychotics)
- Unsanctioned users might start obtaining their Schedule 8 drugs elsewhere (eg, more prescription or warehouse theft, internet purchasing)
- Potential for greater stigmatisation of an already marginalised population
- Not all doctors will respond confidently to real-time information.[62]

In a 2014 article, Nielsen and Bruno identified key questions to consider when implementing a prescription drug monitoring program (PMP):

- *Are we monitoring the right prescription drugs?* The proposed PMP will not monitor weaker opioids such as tramadol, codeine-paracetamol combinations and the majority of benzodiazepines despite these also being important contributors to morbidity and mortality.
- *At what threshold of medication dispensing will the PMP trigger a response?* Simple triggers such as the receipt of opioid prescriptions from more than one prescriber could result in false positives, which can unnecessarily stigmatise patients who are using medications appropriately. There is the potential for 'flags' to be set that specify clinical requirements for regulatory approval. Expert input is required to reach an agreement on what these 'flags' might be.
- *Who will respond and how?* Introducing a PMP raises questions of (i) whether there is sufficient person power in the regulatory body to be able to respond to requirements for regulatory approval in a timely manner, and (ii) of the ability to access review from specialists in a timely manner. Action will also be required to provide pharmacists with the skills to communicate with patients who are 'flagged'.
- *What represents 'best practice' in responding to the needs of those identified through PMP?* Current treatment pathways for those dependent on prescription medications people are not well defined, with few services

[62] Shand F et al, Real-time monitoring of Schedule 8 medicines in Australia: evaluation is essential, *Medical Journal of Australia,* 2013, 198(2), p 80-81.

sufficiently equipped to manage the common presentation of concurrent addiction and pain.[63]

7.4 Commonwealth Pain MedsCheck

In January 2018, shortly before the rescheduling of codeine took effect (see section 6.1), Commonwealth Health Minister Greg Hunt announced that the Government was "providing $20 million to run a new trial program, through community pharmacies across Australia, which will support people suffering from on-going chronic pain".[64] The Pain MedsCheck will involve professional pharmacist face-to-face consultations with patients to review their medication and develop a written action plan, incorporating education, self-management and referral to doctors or other experts where additional support is required.

7.5 NSW Government policy

In August 2016, in response to a budget estimates question, the NSW Minister for Health, Jillian Skinner, outlined a range of actions that the NSW Government was taking to address pharmaceutical drug misuse.[65] These included:

- *The Discomfort Zone – Managing Difficult Consultations*: A training program to assist prescribers who feel pressured to prescribe drugs inappropriately;
- The *Program of Experience in the Palliative Approach*: Provides resources for clinical workforce placements and workshops for health professionals in the treatment of pain management;
- Using the *National Drug Control System* to monitor supplies of Schedule 8 opioid drugs to pharmacies, to assist in prioritising and initiating investigations into prescribing and supply by pharmacists;
- Publication of guidelines by the NSW Therapeutic Advisory Group to assist prescribers in preventing and managing problems with prescribing of opioid drugs for chronic non-cancer pain;
- The proposed national prescription monitoring program;
- The *NSW Pain Management Plan 2012-2016*;
- *Considering outcomes of take-home Naloxone trial:* Naloxone, a drug

[63] Nielsen S and Bruno R, Implementing real-time prescription drug monitoring: Are we ready? *Drug and Alcohol Review*, 2014, 33(5), p 463-465. See also Ogeil R, Prescription drug monitoring in Australia: capacity and coverage issues, *Medical Journal of Australia,* 2016, 204(4), p 148; and Mackee N, Real-time prescription monitoring can't work alone, *Medical Journal of Australia Insight,* October 2016, 41, [online];

[64] Hunt G, Pharmacy trial to support patients with chronic pain, Media Release, 25 January 2018.

[65] Legislative Council of NSW General Purpose Standing Committee No. 3, *Budget Estimates 2016-17 – Supplementary Questions - Responses to questions relating to the Health portfolio*, 30 August 2016, p 22-23.

which reverses opioid overdoses, was successfully trialled by the South Eastern Sydney Local Health District Drug and Alcohol Service;

- Increasing access to the Opioid Treatment Program.

8. POLICY RECOMMENDATIONS

8.1 NSW Coroner

In June 2014, NSW Deputy State Coroner Forbes made findings in relation to the deaths "of three unrelated persons who at the time of their death were found to have dangerous quantities of addictive prescription medication in their system."[66] In all three cases, the deceased had obtained prescriptions from a number of different doctors. Coroner Forbes made several recommendations to address pharmaceutical drug misuse, including that the NSW Health Minister consider:

- steps that can be taken to implement a real-time web based prescription monitoring program available to, at least, pharmacists and general practitioners within 12 months; and consider including all benzodiazepines within this monitoring program;

- any additional steps that can be taken to educate pharmacists and general practitioners on the ability to report inappropriate prescribing to the NSW Ministry of Health's Pharmaceutical Services Unit on the means of identifying inappropriate prescribing, and on the authority requirements when prescribing Schedule 8 drugs;

- imposing a requirement that a doctor should not commence prescribing a Schedule 8 drug or a benzodiazepine without making enquiries to verify the patient's prescribing history or if not practicable, such supply should be limited to that which is necessary until the history can be obtained; and

- expanding the restrictions on prescribing Schedule 8 drugs in sections 27 to 29 of the *Poisons and Therapeutic Goods Act 1966* to also cover a list of restricted drugs of dependence.

Additionally, Coroner Forbes recommended that the Secretary of the Department of Health move all benzodiazepines to Schedule 8 of the Poisons Standard; and that the Commonwealth Health Minister consider:

- working with the Pharmaceutical Society of Australia, the Pharmacy Guild and other relevant peak bodies to facilitate access to, and promote the use of, the Prescription Shopping Hotline;

- adopting mechanisms to make it compulsory for all medical prescribers to

[66] State Coroner's Court of NSW, *Inquest into the deaths of Christopher Salib, Nathan Attard and Shamsad Akjtar*, Deputy State Coroner Forbes, 27 June 2014.

be registered under the Prescription Shopping Program; and

- the efficacy of the Prescription Shopping Program and consider what, if any, means might be adopted to assist in ensuring that the system is used by practitioners and that it enables prompt identification of the abuse of prescription medications.

Recommendations were also made to the Royal Australian College of General Practitioners and the Pharmacy Guild of Australia, with the aim of these organisations better educating their members about prescription drug misuse.

The current inquiry being conducted by the NSW Coroner's Court into six opioid overdose deaths (mentioned in the introduction) is due to resume in August 2018, with findings expected before the end of the year.[67]

8.2 Victorian Parliamentary Committee

On 27 March 2018, a Victorian Parliamentary Committee tabled a report on its inquiry into drug law reform.[68] In relation to pharmaceutical drugs, the Committee made the following recommendations:

> **RECOMMENDATION 35:** In the short term, the Victorian Government, in conjunction with the Australian Medical Association and other relevant medical bodies, develop prescription opioid medication guidelines for general practitioners and training on appropriate prescribing practices. This should include guidance on monitoring patients, lowering dosages when appropriate, education on the risks of dependence, and effective pain relief alternatives to such medication.
>
> **RECOMMENDATION 36:** The Victorian Government develop and promote a sector-wide stewardship trial program for the medical profession (hospitals, specialist services and general practitioners) based on the Alfred Health model to promote and audit best practice regarding the prescribing and use of medications with potential for misuse (such as analgesics and benzodiazepines). This should be accompanied with promotion and education of best practice in this area and of appropriate attitudes towards pain relief among health professionals. The program should also be accompanied with an evaluation.
>
> **RECOMMENDATION 37:** The Victorian Government develop resources and support or conduct awareness raising campaigns targeting the broader community about the safe and appropriate use of prescription medications for pain relief and promoting the role of non-pharmacological treatments for certain conditions (e.g. stress, anxiety and chronic pain). This could start with a targeted campaign that aims to reach patients in health settings and expand to a broader audience if required.

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[67] Reddie M, *Australia on brink of prescription painkiller epidemic, doctors say*, *ABC News,* 13 May 2018

[68] Legislative Council of Victoria Law Reform, Road and Community Safety Committee, *Inquiry into drug law reform*, 27 March 2018.

RECOMMENDATION 38: The Victorian Government work with the Commonwealth Government to review the fee structure for dispensing medication with potential for misuse, so that the volumes prescribed and dispensed be based on individuals' needs. Fee structure changes could include: incentivising pharmacies to dispense fewer tablets and subsidising patients who receive smaller amounts of medications. As part of this, the Victorian Government should work with the Pharmacy Guild of Australia and other relevant bodies regarding the role of pharmacies in improving dispensing practices.

RECOMMENDATION 39: The Victorian Government adopt measures to ensure the effectiveness of the real-time prescription monitoring (RTPM) system and prevent the diversion of patients with prescription misuse issues to the illicit drug market, including:

- adequately resourcing the alcohol and other drug public treatment sector to accommodate the likely influx of demand resulting from patients identified in the RTPM system with opioid dependency

- as part of Department of Health and Human Service's workforce development and training, ensure that health professionals are equipped to appropriately deal with patients identified in the RTPM system with substance use issues, for example through providing immediate and seamless access to harm reduction and/or treatment services, such as opioid substitution therapies.[69]

9. UNITED STATES POLICY RESPONSES

9.1 The prescription opioids epidemic

In 2011, the US Centers for Disease Control and Prevention issued a media release titled *Prescription painkiller overdoses at epidemic levels*. It stated:

> The death toll from overdoses of prescription painkillers has more than tripled in the past decade according to an analysis in the CDC Vital Signs report released today. This new finding shows that more than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
>
> "Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined," said CDC Director Thomas Frieden, M.D., M.P.H. "States, health insurers, health care providers and individuals have critical roles to play in the national effort to stop this epidemic of overdoses while we protect patients who need prescriptions to control pain."[70]

[69] Legislative Council of Victoria, note 68, p xxxiii; and Chapter 15 (Pharmaceutical Drugs). See also Chapter 17 (Overdose prevention strategies) and Chapter 14 (Medication assisted treatment for opioid dependence).

[70] Centers for Disease Control and Prevention, *Prescription painkiller overdoses at epidemic levels*, Media Release, 1 November 2011.

According to Maxwell, a number of different factors contributed to this problem:

> ...including inappropriate or incorrect prescribing; a variety of drug sources (both legal and illegal); belated governmental response; and aggressive marketing for off-label use by pharmaceutical companies. While physicians can prescribe medications for other than their Food and Drug Administration (FDA)-approved indications if in their professional judgment it is both safe and effective, pharmaceutical companies are not allowed to promote a drug except for its approved indications. In addition to these factors, there has been an increase in opioid prescriptions written for analgesia because of emerging clinical attention to the under-treatment of pain and the need to combat pain.[71]

In April 2011, President Obama released a *Prescription Drug Abuse Prevention Plan*, which outlined action in four major areas:

1. *Education:* Educating the public and healthcare providers to increase awareness about the dangers of prescription drug misuse, and about the ways to appropriately dispense, store, and dispose of controlled substance medications.
2. *Tracking and monitoring:* Enhancing and increasing the use of Prescription Drug Monitoring Programs (PDMPs) to provide opportunities for early intervention and detect therapeutic duplication and interactions between drugs.
3. *Proper medication disposal:* Developing consumer-friendly and environmentally responsible prescription drug disposal programs to help limit the diversion of drugs, as most people who use these drugs non-medically obtain them from family and friends.
4. *Enforcement:* Providing law enforcement agencies with the support and tools they need to expand their efforts to shut down "pill mills" (pain management clinics that prescribe drugs inappropriately) and decrease diversion.[72]

A 2016 Progress Report noted that the nation had "made substantial progress in implementing the four pillars".[73] Progress is summarised in Table 4.

[71] Maxwell J, The prescription drug epidemic in the United States: A perfect storm, *Drug and Alcohol Review,* 2011*,* 30(3), p 264-270.

[72] Executive Office of President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, 2011.

[73] Executive Office of the President, *National Drug Control Strategy 2016,* 2016, p 66.

Table 4: Progress in implementing the Prescription Drug Abuse Prevention Plan

Pillar	Progress
Education	In 2015, medical organisations committed to train 540,000 controlled substance providers on pain management and opioid prescribing. In 2016, the Centers for Disease Control and Prevention released a *Guideline for Prescribing Opioids for Chronic Pain*.
Tracking and monitoring	49 US states and Washington DC now have operational PDMPs. Two electronic data sharing hubs are operational, enabling 43 states to share PDMP data with at least one other state.
Proper medication disposal	In 2014, the Drug Enforcement Administration (DEA) issued a new rule governing the secure disposal of controlled substances. This helped implement the *Responsible Drug Disposal Act of 2010*, which expands options to collect unused controlled substances, and allows for expanded 'takeback' events, mail-back programs, and the placement of collection receptacles at police departments, pharmacies, and some hospitals.
Enforcement	The *DEA 360 Strategy* coordinates law enforcement operations that target drug trafficking organisations; and it engages drug manufacturers, wholesalers, practitioners, and pharmacists to limit the diversion of prescription pain medications. The DEA has continued efforts to crack down on 'pill mills' and doctor shopping, and is working to thwart internet dealing in controlled substances.

The Progress Report also noted action in other policy areas:

- A *National Pain Strategy* was released in 2016;
- Most states have enacted statutes that expand access to Naloxone or provide 'Good Samaritan' protections for possession of a controlled substance if emergency assistance is sought for a victim of an opioid overdose. Federal, state, tribal, and local agencies and stakeholders across the country have increased the availability and use of Naloxone;
- Through funding and other measures, access has been increased for Medication-Assisted Treatment of opioid dependence.

A 2016 article commented on the effectiveness of State government policies to address prescription opioid misuse:

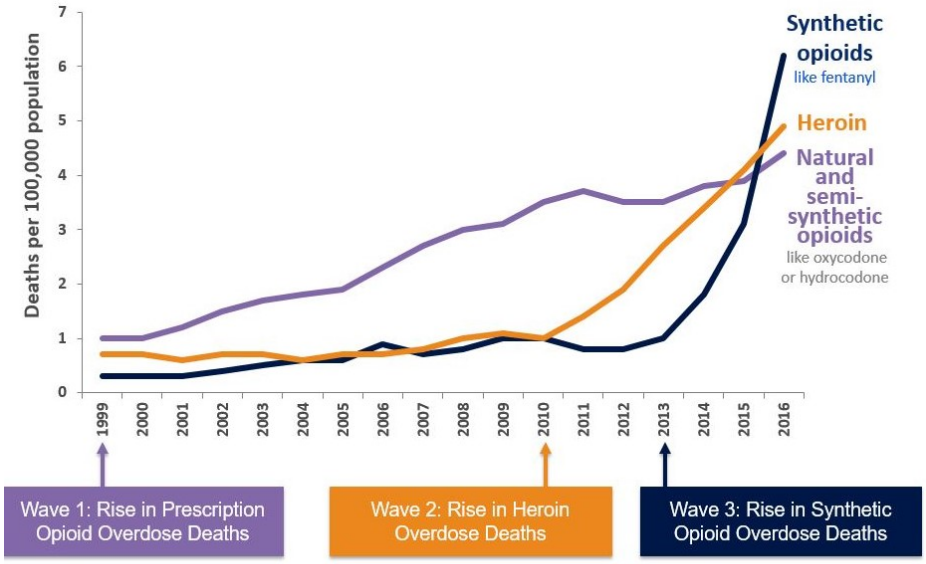
> Implementation of many of these policies is recent, and few rigorous evaluations have been conducted to examine the effects of these statewide policies. However, increasing evidence supports the effectiveness of several specific policies, including expansion of drug take-back and Prescription Drug Monitoring Programs. More broadly, policy changes show promise in enacting and enforcing evidence-supported prescribing practices that reduce risk for abuse and diversion while

maintaining or improving the clinical management of pain.[74]

9.2 The opioids crisis

More recently, the focus in the US has been on an 'opioids crisis' involving both prescription opioids and illegal opioids (including heroin and illicitly manufactured synthetic opioids). In 2016, 42,000 people died from opioid overdoses, more than any year on record.[75] The timeline of this crisis in the US is illustrated below.

Figure 6: Three waves in the rise of opioid overdose deaths: 1999 to 2016[76]



SOURCE: National Vital Statistics System Mortality File.

In October 2017, President Trump declared the opioid crisis a national public emergency.[77] The following month, the President's Commission on Combating Drug Addiction and the Opioid Crisis produced its final report, making 56 recommendations across four broad areas:[78]

1. Federal funding and programs;
2. Opioid addiction prevention;
3. Opioid addiction treatment, overdose reversal, and recovery; and
4. Research and development.

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[74] Brady K, McCauley J and Back S, Prescription Opioid Misuse, Abuse, and Treatment in the United States: An Update, *American Journal of Psychiatry* 2016, 173, p 18-26.

[75] Centers for Disease Control and Prevention, *Opioid overdose* [website – accessed 5 March 2018].

[76] Centers for Disease Control and Prevention, note 75.

[77] The White House, *President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis*, Fact Sheet, 26 October 2017.

[78] C Christie, *Final Report of the President's Commission on Combating Drug Addiction and the Opioid Crisis*, 1 November 2017.

Some of the opioid addiction prevention recommendations are outlined below.

Table 5: Recommendations to prevent opioid addiction

Area	Recommendation
School Prevention Strategy	Collaborating with states on student assessment programs such as Screening, Brief Intervention and Referral to Treatment.
Public education campaigns	Funding and collaborating with the private sector and non-profit partners to design and implement a wide-reaching national media campaign addressing the danger of opioids and associated stigma.
Opioid prescription practices	• Working with stakeholders to develop model legislation and policies that ensure informed patient consent prior to an opioid prescription for chronic pain; • Coordinating the development of a national curriculum and standard of care for opioid prescribers; • Developing a model training program, to be disseminated to all levels of medical education, on screening for substance use and mental health status to identify at-risk patients; • Amending the *Controlled Substances Act* to allow the DEA to require all prescribers desiring to be relicensed to prescribe opioids to participate in an approved education program.
Enhancements to PDMPs	Enacting the *Prescription Drug Monitoring Act* to mandate states that receive grant funds to comply with PDMP requirements such as data sharing.
Reimbursement for non-opioid pain treatments	Reviewing and modifying rate-setting policies for Medicare and Medicaid that discourage the use of non-opioid treatments for pain.

On 29 December 2017, the Trump Administration published its response, which broadly agreed with the Commission's recommendations.[79] Then in March 2018, President Trump launched an *Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand.* It has three major parts:

- Reduce drug demand through education, awareness, and preventing over-prescription.
- Cut off the flow of illicit drugs across our borders and within communities.

[79] White House, *Trump Administration Response to the Final Recommendations of the President's Commission on Combatting Drug Addiction and the Opioid Crisis*, 29 December 2017

- Save lives now by expanding opportunities for proven treatments for opioid and other drug addictions.[80]

The first part included launching a national campaign to raise public awareness about the dangers of prescription and illicit opioid use, and implementing a Safer Prescribing Plan to achieve the following objectives:

- Cut nationwide opioid prescription fills by one-third within three years.
- Ensure that 75 percent of opioid prescriptions reimbursed by Federal healthcare programs are issued using best practices within three years, and 95 percent within five years.
- Ensure that at least half of all Federally-employed healthcare providers adopt best practices for opioid prescribing within two years, with all of them doing so within five years.
- Leverage Federal funding opportunities related to opioids to ensure that States transition to a nationally interoperable Prescription Drug Monitoring Program network.[81]

10. CONCLUSION

Over the past decade in Australia there has been an increase in the rate of pharmaceutical drug misuse and a marked rise in overdose deaths involving these drugs. In 2012, a national framework of action was developed to address the problem. One of the framework's key priorities – a national real-time prescription monitoring program – has not yet eventuated. Tasmania has had such a system since 2012 while Victoria and the ACT are currently introducing State-based systems.

Both Commonwealth and State legislation regulates the supply of pharmaceutical drugs. A recent change at the Commonwealth level was the rescheduling of commonly used painkillers containing codeine so that they can now only be obtained by prescription. The Commonwealth TGA is also currently consulting on a range of regulatory options for dealing with the misuse of strong opioids. Meanwhile, the medical profession has developed new guidelines in relation to drugs of dependence.

The NSW Government has undertaken a range of actions including:

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[80] White House, *President Donald J. Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand*, 18 March 2018.

[81] White House, *President Donald J. Trump's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand*, 18 March 2018. For further reading on US policy, see Department for Health and Human Services, *National Opioids Crisis*, [website – accessed 5 March 2018]; National Conference of State Legislatures, *Prescription For America's Opioid Addiction*, [website – accessed 5 March 2018]; Bagalman E et al, *Prescription Drug Abuse*, Congressional Research Service, 23 February 2016; *Prescription Drug Monitoring Programs*, Congressional Research Service, 24 May 2018; and Global Commission on Drug Policy, *The Opioid Crisis in North America*, Position Paper, October 2017.

- programs to educate prescribers;
- monitoring supplies of Schedule 8 drugs to pharmacies;
- working towards a national prescription monitoring program;
- releasing a pain management strategy;
- considering the outcomes of take-home Naloxone trials; and
- increasing access to the Opioid Treatment Program.

Other policy measures that could be adopted in NSW are those recommended in a 2014 NSW Deputy State Coroner's report and a 2018 Victorian Parliamentary Committee report. US policy responses are also worth considering. The US programs that allow for the collection of unused prescription drugs may be of particular interest in light of the evidence that family and friends are a significant source for those who misuse pharmaceutical drugs.