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Regulatory Impact Statement – Proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018

Department of Health and Human Services

2018

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Glossary

Acronym	Full name
ABS	Australian Bureau of Statistics
ADHD	Attention deficit hyperactivity disorder
AHPRA	Australian Health Practitioner Regulation Agency
AIHW	Australian Institute of Health and Welfare
AR-DRG	Australian Refined Diagnosis Related Group
AOD	Alcohol and Other Drug (treatment services)
ATO	Australian Taxation Office
BCR	Benefit-to-cost ratio
CDC	Centers for Disease Control and Prevention
EAG	External Advisory Group
ED	Emergency Department
ERRCD	Electronic Recording and Reporting of Controlled Drugs
DHHS	Victorian Department of Health and Human Services
DHS	Commonwealth Department of Human Services
GP	General Practitioner
KPI	Key Performance Indicator
MBS	Medical Benefits Schedule
MSIA	Medical Software Industry Association
NEP	National Efficient Price
NPS	National Prescribing Service
NPV	Net Present Value
OBPR	Office of Best Practice Regulation
OCBR	Office of the Commissioner for Better Regulation
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PES	Prescription Exchange Service
PV	Present Value
RIS	Regulatory Impact Statement
RTPM	Real-Time Prescription Monitoring
S4	Schedule 4 – Prescription Only Medicine
S8	Schedule 8 – Controlled Drug
TGA	Therapeutic Goods Administration
UDG	Urgency Disposition Group
VSL	Value of Statistical Life

Executive Summary

The Victorian Government has committed to implement a Real-Time Prescription Monitoring (RTPM) system in order to reduce the growing harms and deaths from high-risk prescription medicines.

Prescription medicine harms in Victoria

Over recent years, there has been a significant rise in the number of deaths involving prescription medicines in Victoria. The number of overdose deaths in Victoria involving pharmaceutical medicines rose from 295 in 2009 to 372 in 2016, a rise of 5.5 to 6 deaths per 100,000 people (Coroners Prevention Unit, 2017). Of the deaths that occurred in 2016, 87% involved benzodiazepines and 62% involved licit opioids. Since 2012, the number of deaths involving pharmaceutical medicines each year has surpassed the annual road toll.

At present, it is difficult for practitioners to identify harmful use of prescription medicine. While pharmacists are required to keep records of prescription medicines supplied to patients, the records are not linked centrally and cannot be viewed by doctors or other pharmacies.

SafeScript, Victoria's real-time prescription monitoring system

In response to the increasing harms from prescription medicines, and the need for prescribers and pharmacists to gain increased visibility over the medicine usage of their patients, the Victorian Government has committed to implement SafeScript, Victoria's real-time prescription monitoring system. SafeScript will enable prescribers and pharmacists to detect potential unsafe use of prescription medicines, and inform safe prescribing practices.

SafeScript uses computer software to enable patient prescription and pharmacy dispensing records for certain medicines to be transmitted in real-time to a centralised database which can then be accessed by doctors and pharmacists during a consultation. SafeScript acts as an important public health initiative, aiding decision making and facilitating earlier intervention.

The objectives of SafeScript are to:

- Promote safe supply, prescription and dispensing practices;
- Reduce harm from monitored poisons and other high risk medication; and
- Facilitate evaluation and research into the use of high-risk medicines in the community.

Legislation overview

Legislation which establishes the legal framework to implement SafeScript passed through the Victorian Parliament in October 2017. The *Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Bill 2017* outlines the key parameters necessary for DHHS to create a database for the purposes of prescription monitoring in Victoria. These include:

- Enabling the monitoring of all S8 poisons plus scope to include other high-risk medicines
- A requirement for medical practitioners, nurse practitioners and pharmacists to check the SafeScript before writing or dispensing a prescription for a high-risk medicine
- A requirement for certain entities to provide records and information to SafeScript.

The primary legislation establishes the legal framework to enable Victoria to mandate the use of SafeScript before writing or dispensing a prescription for a high-risk medicine. As Victoria will be the first state to roll out a prescription monitoring system of this scale, and to ensure it is embedded in clinical practice, appropriate transitional arrangements will be in place before this requirement comes into effect. The proposed Regulations provide for an 18 month period where the mandatory requirement for medical practitioners, nurse practitioners and pharmacists to check SafeScript is suspended until 1 April 2020 to allow clinicians to familiarise themselves with the use of SafeScript and incorporate it into their clinical practice.

The legislation also enables specific requirements necessary for the effective operation of SafeScript to be prescribed in regulations. The proposed Regulations include the full list of medicines to be monitored, which specific entities are required to provide data and what the records must contain, as well as the exceptions from mandatory use.

Options for regulations

DHHS has undertaken an analysis of the options available for regulating SafeScript in Victoria, which is contained in this document. These options fall under four design choices:

Design Choice 1 – The selection of medicines to be included in SafeScript

The first design choice is concerned with the choice of medicines to be monitored under SafeScript. The options considered are to (1) only monitor S8 poisons (for which additional regulatory controls under the S8 permit system are currently in place in Victoria), or to (2) monitor selected high-risk S4 poisons in addition to the S8 poisons already monitored.

The high-risk S4 poisons to be monitored were chosen based on recommendations made by an expert advisory group which considered the findings of a literature review that examined the harms conferred by various S4 poisons. The advisory group recommended that in addition to S8 poisons, that monitoring would be appropriate for all benzodiazepines, z-drugs, and quetiapine from the start of implementation. Combination analgesics containing codeine were recommended for inclusion at a later stage of implementation. While a number of other medicines were considered (such as gabapentin, pregabalin and tramadol), they were regarded to be not sufficiently high-risk in comparison to the medicines included in SafeScript.

The options analysis for Design Choice 1 uses a cost-benefit analysis to compare Options 1 and 2. While costing more to implement, the analysis suggests that Option 2 offers a greater net social benefit of $2 billion, with a benefit-to-cost ratio of 11.63 (Table i). This large benefit is predominantly due to it leading to a reduction in the number of deaths that are associated with the selected S4 poisons.

Table i: Cost-benefit analysis results for the ten-year period 2018/19-2027/28, associated with alternative medicine options (present values)

	S8s only	S8s and selected S4s
Total costs	$131.5 million	$189.1 million
Total benefits	$717.4 million	$2199.2 million
Net benefit	$585.9 million	$2010.1 million
Benefit-to-cost ratio	5.46	11.63
Prevented deaths	163	501

As with any cost-benefit analysis, uncertainty is present in the assumptions used as well as projected trends such as future prescription quantities and deaths from overdose. We have therefore undertaken sensitivity analysis by altering some of the underlying parameters to test a range of scenarios including where (a) SafeScript prevents less deaths than initially estimated (5% effectiveness down from 12% effectiveness), (b) accessing SafeScript takes longer than initially estimated (increasing the time to check SafeScript from 1 minute to 3 minutes), (c) increasing the Government funding necessary to implement SafeScript (from $29.5 million to $60 million) and (d) increasing the amount of time allocated to SafeScript training (from 30 minutes to 120 minutes). When all these scenarios are in place, the monitoring of S8s and selected S4s in RTPM still provides a net benefit of $497.3 million, with a benefit-to-cost ratio of 2.07.

Design Choice 2 – The selected settings and circumstances under which it is not mandatory for health professionals to check SafeScript

The second design choice concerns what exceptions should be included when use of SafeScript becomes mandatory. These are qualitatively assessed in terms of the risk of harm present in these settings and circumstances, and the costs that would be imposed by monitoring these settings and circumstances. The patient groups considered are:

- **Options 1-4 – Hospital in-patients, emergency department patients, prisoners, patients in police gaols, aged care residents:** these settings are considered a low risk for harmful use of prescription medicines, as supply in these settings is within a closed environment. Therefore, Options 1-4 are considered appropriate exceptions.
- **Option 5 – Palliative care patients:** patients diagnosed with a terminal illness may be prescribed large quantities of prescription medicines for palliative care purposes. Given the prognosis is limited, the aims of therapy in these cases are of increasing quality of life, and treatment is under close supervision, Option 5 is considered an appropriate exception.
- **Option 6 – Cancer patients:** a diagnosis of cancer was previously considered likely to be terminal, however with the advances in treatment, this is no longer the case in some circumstances. As overall cancer survival rates are increasing, patients with cancer may be prescribed higher doses of opioids for longer

periods of time than previously. The risk of prescription medicine overdose increases when patients are prescribed higher doses of opioids for an extended period. Therefore, Option 6 is not considered an appropriate exception.

- **Option 7 – Patients supplied with seven days' or less of medicine**: in several prescription monitoring systems in the United States, health professionals are exempted from checking when providing a short supply of medicines, due to a lesser perceived potential for harm stemming from shorter periods of treatment. However, even when smaller quantities of medicines are prescribed, it is still possible for such instances of supply to cause serious harm, particularly where patients visit multiple prescribers to obtain various high-risk medicines and those prescribers are not aware of one another's actions. Therefore, Option 7 is not considered an appropriate exception.

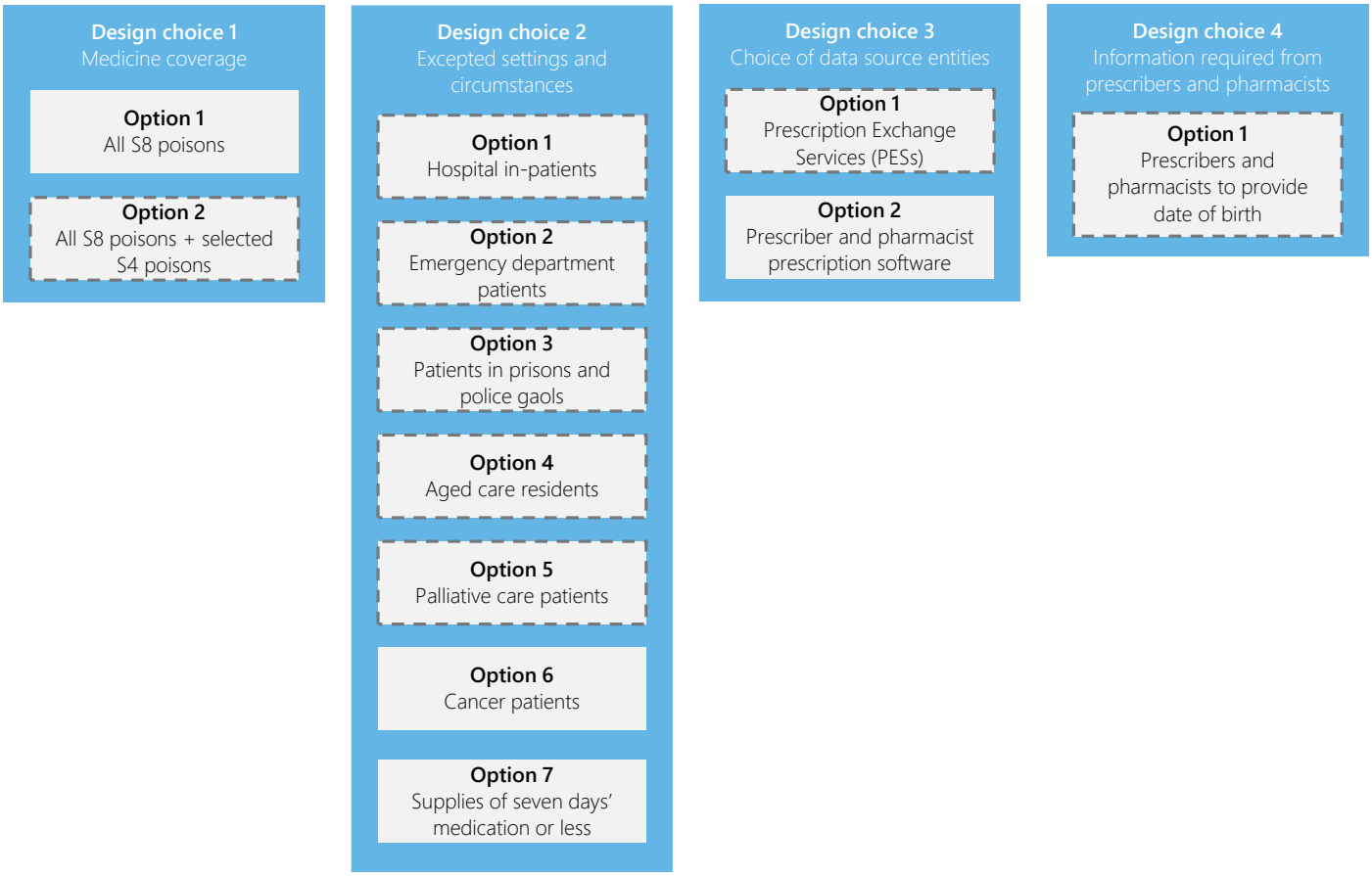
Design Choice 3 – The entities required by the Regulations to provide information to SafeScript

Two main options exist for data source entities that will be able to populate SafeScript with information on prescriptions. The first option is the use of Prescription Exchange Services (PESs), which are electronic systems that are connected to medical prescribing and pharmacy dispensing systems to collect prescription records, whereas the second option involves requiring every pharmacist to individually provide records to SafeScript through records entered in pharmacy dispensing software. While the second option is the method for how records are collected in Tasmania's RTPM, this was deemed unsuitable in Victoria due to the scale of implementation in Victoria and the efficiency of obtaining data from only two PESs as opposed to integrating with at least 12 separate pharmacy systems. Leveraging the PES infrastructure also has advantages in providing a system that will be scalable at a national level and a user experience that is incorporated into existing clinical workflows. Therefore, DHHS considers that the nomination of PESs as data source entities is the appropriate option.

Design Choice 4 – The information required to be provided to SafeScript for data matching purposes

In order to be an effective source of information for health professionals, a reliable and robust method of matching patient prescription records is necessary. While the use of a common health identifier, such as a patient's Medicare number, would be useful, the use of this identifier is limited to the provision of a medical or pharmaceutical benefit under the Medical Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS), and it cannot be collected by SafeScript for the purposes of data matching. The option of requiring the collection of a patient's date of birth is considered appropriate to improve data matching. With the majority of prescribers and pharmacists using electronic software that facilitates the recording of a patient's date of birth, the collection of this information will not convey a large regulatory burden.

A summary of the regulatory design choices, and the options considered for each design choice is shown below. The options that have been chosen for implementation are highlighted.



Under a 'worst case' scenario the preferred options will have costs of $470.5 million (in present value terms, between 2018-19 and 2027-28) and estimated benefits of $974.3 million over the same period. However, DHHS expects that costs are likely to be much lower and the benefits much higher, resulting in an estimated net benefit of $2 billion (see Section 4 for detailed analysis).

Implementation plan

SafeScript will initially be implemented in a single region, and then evaluated, before being rolled out across Victoria. Prior to April 2020 it will not be mandatory for medical practitioners, nurse practitioners and pharmacists to check SafeScript in order to allow clinicians to become familiarised with the use of SafeScript and incorporate it into their clinical practice.

As part of this roll-out, DHHS will develop and implement a public awareness campaign. This will include a change management plan in relation to the changes to the legislation and regulations.

Training focussed on augmenting the clinical skills of the primary care workforce is a key aspect of implementation that was identified during the planning work for SafeScript. Training is currently being developed and will be delivered primarily to medical practitioners and pharmacists. A partnership with the Victorian Primary

Health Networks and NPS MedicineWise has been established to deliver the training. Materials to be covered in the training will be created after undertaking an analysis of needs and gaps with stakeholders. The financial cost of this training is included in the Victorian Government's $29.5 million funding towards SafeScript.

Evaluation strategy

In accordance with good regulatory practice, the Government is developing an evaluation strategy to measure the efficiency and effectiveness of the proposed Regulations, and SafeScript more generally. The evaluation strategy will be refined during 2018 and prior to SafeScript commencing.

DHHS proposes that the evaluation strategy for SafeScript will comprise four distinct elements:

1. Baseline – gathering a range of data on current outcomes in order to provide a baseline for future comparisons
2. Implementation – continuing evaluation during the implementation phase to 'fine tune' the SafeScript rollout
3. Ongoing monitoring via the collection of a range of data on an annual basis
4. Three-year review – a more comprehensive mid-term review after three full years of SafeScript to determine whether it is achieving its objectives

DHHS will be responsible for evaluating and reporting on the effectiveness of SafeScript.

Once SafeScript is in place across the state, DHHS will undertake ongoing evaluation of the system. The purpose of this would be to ensure that SafeScript is operating efficiently and effectively at a state-wide level.

This would provide DHHS with a clear indication of the extent of which SafeScript is achieving the intended objectives and benefits, as well as whether there are any unintended consequences that need to be managed.

1 Background

The purpose of this Regulatory Impact Statement (RIS) is to evaluate options to address the problems that real-time prescription monitoring (RTPM) seeks to address, and explain why the Department of Health and Human Services (DHHS) considers the proposed Regulations are the best way to support the legislation which enables RTPM in Victoria.

1.1 Purpose of the RIS

The purpose of this Regulatory Impact Statement (RIS) is to evaluate options for regulation of RTPM, as outlined in the Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018.

A Regulatory Impact Statement (RIS) is required under the *Subordinate Legislation Act 1994* for Regulations that are 'likely to impose a significant economic or social burden on a sector of the public'.

The primary focus of the analysis relates to implementation matters that are detailed in the proposed Regulations, including the medicines to be monitored in Victoria's RTPM system and the circumstances in which exceptions from mandatory use will be provided.

While the RIS assesses what is being proposed in regulations to support the primary legislation, its purpose is not to reassess matters in the primary legislation.

1.2 The regulation of prescription medicines

The supply of prescription and pharmacy-only medicines in Victoria is governed by the *Drugs, Poisons and Controlled Substances Act 1981* (the Act) and the Drugs, Poisons and Controlled Substances Regulations 2017 (the Regulations). Together, the primary legislation and subordinate regulations limit the manufacture, distribution and use of drugs and poisons to those people who are properly trained and equipped. They also provide regulatory controls on the prescribing and supply of medicines in an effort to promote safe patient management. DHHS is responsible for administering the Act and the Regulations in Victoria.

All medicines registered for use in Australia must be approved by the Therapeutic Goods Administration (TGA). The TGA also oversees the classification of medicines in Australia into one of several schedules, according to the level of regulatory control required to ensure public health and safety. A valid prescription is required for both Schedule 4 (S4) - Prescription Only Medicines - and Schedule 8 (S8) - Controlled Drug Medicines - according to the TGA's *Standard for the Uniform Scheduling of Medicines and Poisons*. S8 poisons carry the highest risk of harm and are subject to greater restrictions and control on their supply.

1.3 What is real-time prescription monitoring?

Real-time prescription monitoring (RTPM) uses computer software to enable patient prescription and pharmacy dispensing records for certain medicines to be transmitted in real-time to a centralised database which can then be accessed by doctors and pharmacists during a consultation. The system acts as an important public health initiative, aiding decision making and facilitating earlier intervention.

The monitoring of prescriptions was first recommended in 1980 by the Australian Royal Commission of Inquiry into Drugs (Williams, 1980). Since 2012, there have been over 30 coronial findings which have recommended or provided support to the implementation of RTPM in Victoria. All key professional bodies including the Australian Medical Association, the Royal Australian College of General Practitioners, the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia have also strongly advocated for RTPM.

Tasmania is the first state in Australia to have implemented a real-time prescription monitoring system. In 2012, the Tasmanian system was purchased and upgraded by the Commonwealth Department of Health. The Commonwealth software, known as the Electronic Recording and Reporting of Controlled Drugs (ERRCD), was provided to all states and territories in 2013 to allow each jurisdiction to implement a nationally-consistent system. However, limited progress has been made to implement the ERRCD at a national level. In July 2017, the Commonwealth announced it will allocate $16 million in funding towards the implementation of a national roll-out of the ERRCD.

1.4 Victorian Government action

In the 2016-17 State Budget, the Victorian Government announced a $29.5 million commitment to implement SafeScript, Victoria's RTPM system. The core intent of this public health initiative was to reduce the amount of harm and death of Victorians arising from high-risk prescription medicines.

The funding will be used to roll out the software system to all medical clinics, pharmacies and hospitals throughout Victoria, as well as providing training and support packages for doctors and pharmacists. Funding will also be provided for minor enhancements to counselling and treatment services for patients who are identified as misusing prescription medicines.

In August 2017, the Victorian Government announced that due to the limitations of the Commonwealth software, it was no longer continuing with implementation of the ERRCD, and instead a specific fit-for-purpose software will be built for Victorian clinicians.

The proposed Regulations will enable the implementation of SafeScript, Victoria's RTPM system, which will be based on obtaining prescription records from Prescription Exchange Services (PES). Prescription Exchange Services are electronic prescription repositories which were developed to support national e-health initiatives, including the electronic transfer of prescriptions. SafeScript will leverage PES infrastructure, which will provide for a system that will be scalable at a national level and a user experience that is incorporated into existing clinical workflows.

With all jurisdictions working together towards implementing a national system, Victoria remains committed to the implementation of national data sharing arrangements to reduce the risk of cross-border issues with safe supply of

> "It doesn't matter how experienced you are, prescription shoppers are difficult to identify. How do you pick someone by looking at them when they are making every effort not to be found?"
>
> **Interviewed pharmacist (28 September 2016)**

prescription medicines. The primary legislation will enable Victoria to enter agreements or memoranda of understanding with any jurisdiction or the Commonwealth, to facilitate the exchange of information between jurisdictions for the purposes of a national system.

1.5 Legislation overview

The *Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Bill* 2017 was introduced into the Victorian Parliament in August 2017. The Bill, which establishes the legislative framework to implement RTPM in Victoria, passed the Legislative Assembly and Legislative Council in September and October 2017 respectively. The legislation amends the *Drugs, Poisons and Controlled Substances Act 1981*, which sets the regulatory controls on the safe supply and use of medicines and poisons in Victoria.

The stated objectives of the Bill are to:

- Promote safe supply, prescription and dispensing practices;
- Reduce harm from monitored poisons and other high risk medication; and
- Facilitate evaluation and research into monitored poisons and the operation of the monitored poisons database.

The legislation specifies two categories of medicines:

- Monitored poisons: these are medicines for which records relating to their supply are included in SafeScript
- Monitored supply poisons: these are medicines where prescribers and pharmacists are required to check SafeScript prior to their prescribing or supply.

To meet its objectives, the Bill outlines the following key requirements:

- That S8 poisons and other *monitored poisons* are to be monitored through SafeScript (referred to in the legislation as the *monitored poisons database*).
- All medical practitioners, nurse practitioners and pharmacists are required to check SafeScript before prescription or supply of a *monitored supply poison*.
- *Data source entities* (to be specified in regulations) are required to provide records and information to SafeScript.

The Bill contemplates the introduction of regulations addressing the following matters:

- Specifying which medicines are monitored poisons and monitored supply poisons
- Specifying the settings and/or circumstances for which health professionals are not required to check SafeScript before prescribing or supplying a medicine monitored by SafeScript
- Specifying the data source entities that will provide records to SafeScript, and what the records must contain.

The primary legislation establishes the legal framework to enable Victoria to mandate the use of SafeScript before writing or dispensing a prescription for a high-risk medicine. As Victoria will be the first state to roll out a prescription monitoring system of this scale, and to ensure it is embedded in clinical practice, appropriate transitional arrangements will be in place before this requirement

comes into effect. The proposed Regulations provide for an 18 month period where the mandatory requirement for medical practitioners, nurse practitioners and pharmacists to check SafeScript is suspended to allow clinicians to familiarise themselves with the use of SafeScript and incorporate it into their clinical practice. This is achieved by specifying all medicines monitored by SafeScript to become *monitored supply poisons* from 1 April 2020.

1.6 Expert advice

DHHS has established an External Advisory Group (EAG) to advise on matters relevant to the implementation of SafeScript in Victoria.

The EAG includes representation across the major medical and pharmacy organisations, as well as other key stakeholder groups, namely:

- Australian Medical Association
- Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists
- Medical Software Industry Association
- Pharmaceutical Society of Australia
- Pharmacy Guild of Australia
- Royal Australasian College of Physicians
- Royal Australian College of General Practitioners
- Rural Doctors Association of Victoria
- ScriptWise – a consumer advocacy non-profit organisation
- Victorian Aboriginal Community Controlled Health Organisation
- Victorian Alcohol and Drug Association
- Victorian Primary Health Networks
- Consumer representatives

Advice from the EAG has informed several key implementation aspects of SafeScript, including those which require regulations to be made, namely the scope of medicines to be monitored and the exceptions from mandatory use.

2 Problem definition

This chapter provides an overview of the problems related to prescription medicines and the need for regulations to effectively implement real-time prescription monitoring in Victoria.

2.1 Trends in the prescribing of and harm caused by prescription medicines

2.1.1 Harms caused by prescription medicines

The impact of harms caused by high-risk prescription medicines range from absence from work, criminal activity, and in more extreme cases, hospitalisation and/or death.

Over recent years, there has been a significant rise in the number of deaths involving prescription medicines in Victoria. The number of overdose deaths in Victoria involving pharmaceutical medicines rose from 295 in 2009 to 372 in 2016, a rise of 5.5 to 6 deaths per 100,000 people (Coroners Prevention Unit, 2017).[1] Of the deaths that occurred in 2016, 87% involved benzodiazepines and 62% involved licit opioids. Since 2012, the number of deaths involving pharmaceutical medicines each year has surpassed the annual road toll (Table 2.1).

Table 2.1: Number of deaths in Victoria caused by pharmaceutical medicine overdose and road trauma

Cause of death	2009	2010	2011	2012	2013	2014	2015	2016
Overdose from Pharmaceuticals	295	266	275	306	313	316	358	372
Road trauma	290	288	287	282	243	248	252	290

Source: Coroners Prevention Unit (2017), TAC *Road Safety Statistics*

A study conducted by the National Prescribing Service (NPS) suggests that the factors correlated with risk of prescription overdose death include being male, aged 35-44, with mental illness and pain (National Prescribing Service, 2014). However, stakeholder consultations with prescribers and pharmacists have stressed that without access to timely information on prescription data, it is difficult to identify all 'at risk' individuals based on a face value assessment.

[1] The deaths per 100,000 people was calculated by dividing the number of overdose deaths in 2009 and 2016 involving pharmaceuticals by the Victorian population in 2009 and 2016, sourced from ABS Demographic Statistics, Catalogue 3101.0 (ABS, 2017), and multiplying the resulting death rate by 100,000.

2.1.2 Trends in prescribing

The increased use of opioids in Victoria (and internationally) has raised concern about excessive and inappropriate prescribing for chronic, non-malignant pain. Opioids are increasingly being prescribed for chronic conditions such as low back pain and arthritic pain for which there is limited evidence of their benefit in long-term use but growing concern about their potential harms (Chou, et al., 2015). This has arisen due to an increase in the multitude of opioid formulations that are now available, such as slow release formulations and patches, which offer more convenient forms of pain relief. The long periods of treatment required by chronic conditions, however, can lead to lessened pain-relieving effects while at the same time introducing dependency. This is one of the main gateways through which people can become addicted to prescription medicines, and fall into inadvertent harmful use.

The increased use of prescriptions has also increased the cost burden to the Australian Government. A 20-fold increase in prescriptions over 15 years has equated to a 32-fold increase in costs to the Commonwealth Government ($8.5 million to $271 million) (Blanch, Pearson, & Haber, 2014). There were 2 million prescriptions for S8 poisons dispensed in Victoria under the Pharmaceutical Benefits Scheme (PBS) in 2016/17 alone. Of these, 616,603 were for oxycodone, at a cost of over $13 million in subsidies (Commonwealth Department of Health and Ageing, 2017).

2.1.3 Obtaining supplies of medicines beyond therapeutic need

Problems with use of high-risk prescription medicines exist on a spectrum. They can range from inadvertent harm associated with inappropriate prescribing practices through to deliberate misuse with the aim of experiencing non-therapeutic effects and/or on-selling the medicines. As such, there are many circumstances which can lead to prescription medications ultimately cause harm to those that take them.

One such circumstance is where patients obtain more medicines than are medically needed by attending multiple doctors and/or multiple pharmacies to obtain medications. While it is not the only circumstance under which prescription medications cause harm, there is evidence from coronial findings to suggest that contributes to a significant number of deaths in Victoria. A recent study from the Coroners Court found that of the 607 overdose deaths in Victoria in 2009-15 where at least one contributing pharmaceutical medicine was known to be prescribed to the deceased, approximately one-quarter of the deaths involved multiple known prescribers of the contributing medicine (Dwyer, Ogeil, Bugeja, Helibronn, & Lloyd, 2017).

There are instances where patients actively seek to obtain large quantities of prescription medicines for non-therapeutic purposes. This has been a contributing factor in the growing number overdose deaths in Victoria (see Box 2.1).

However, there are also situations where patients inadvertently experience harm from prescription medicines such as where individuals who are being treated by a number of different medical practitioners, are prescribed toxic combinations of drugs, resulting in overdose. In instances such as these, due to a lack of co-ordinated care, the medical practitioners are unaware of what other practitioners have already prescribed to the patient (see Box 2.2).

Death from long term addiction

In the three years prior to his death, [the patient] attended 19 different doctors for PBS prescriptions dispensed from 32 different pharmacies. He obtained additional large quantities of medications not recorded on the PBS.

His family and friends were aware of his addiction. His addiction resulted in several episodes of violent behaviour. His performance at work was adversely affected and he lost his job. Financial problems followed, and his relationship broke down.

The patient was aware that his addiction was harmful, and made numerous attempts to control his drug use including getting a friend to lock up his drugs, admissions to residential drug treatment, and help from alcohol rehabilitation programs.

Coronial recommendation: That the Victorian DHHS implement a real-time prescription monitoring program within 12 months, in order to reduce deaths and harm associated with prescription shopping.

Expected effectiveness of RTPM

The extent of prescription shopping observed in this case would have been minimised with RTPM, as it would have been possible for any one of the 19 doctors or 34 pharmacists involved to have identified through RTPM that the patient was obtaining supplies beyond therapeutic need. RTPM reduces the harms and deaths from prescription medicines by enabling health professionals to identify early signs of problematic use and offer interventional support and treatment much sooner before patients develop addiction.

Box 2.1: Case study – extract from 2012 Coronial inquest

Obtaining large quantities of medicines for non-therapeutic purposes may also be for financial gain, rather than for the intention of meeting a drug dependent person's needs, as there exists a strong black market for prescription opioids (Cogger, Dietze, & Lloyd, 2014). These may be used by drug dependent persons, or recreationally as part of a cocktail of drugs. The risk of overdose increases substantially when opioids are combined with illicit drugs such as heroin and opioid replacement therapies (e.g. methadone).

Medicare Australia defines a 'prescription shopper' as someone who has seen six or more doctors in a three month period, or has been supplied a total of 25 or more target PBS items or 50 or more PBS items. Using these criteria, there were 968 prescription shoppers identified in Victoria in 2011-12 (Commonwealth Department of Health (2012). However, these criteria may be considered a conservative measure, as harms from high-risk prescription medicines can occur at lower thresholds which would not be included in these estimates.

2.2 The need for regulations to support RTPM legislation

While the Act establishes the legislative framework for SafeScript, regulations are needed to ensure:

1. That SafeScript targets the sources of risk of harm; and
2. The system is established and operates properly.

2.2.1 Identifying the sources of harm through regulations

In order for SafeScript to target the specific sources of risk of harm, the regulations must specify:

- Which medicines require checking; and
- The settings or circumstances where healthcare professionals are exempt from legislated requirements.

2.2.1.1 Categories of medicines that require monitoring and checking

The legislation requires that any medicine that requires checking before its prescription or supply (a *monitored supply poison)*, must also be a medicine that is monitored by SafeScript. There are no *monitored supply poisons* specified in the legislation, although the legislation specifies all S8 poisons as *monitored poisons*.

Without careful selection of the medicines that are being monitored by SafeScript, it is possible that the aims of the legislation would not be met. The medicines selected for monitoring should be those where there is clear evidence of harms.

Further to this, other effects must be taken into account when considering which medicines to monitor. For example, medicines that are in the same family as those that are causing significant harm, may be causing limited harm in Victoria at present. However, if SafeScript were to only cover the medicines being misused or inappropriately prescribed currently, it is possible that people could switch to those medicines that were not covered by SafeScript. This "squeezed balloon effect" was observed after changes in the scheduling for alprazolam in February 2014: while the scheduling was followed by a drop in deaths involving alprazolam, the number of deaths involving diazepam and clonazepam increased (Austin Health, 2017).

Consequences of lack of information sharing across prescribers

[The patient] was being treated for a myriad of physical and mental health conditions (including chronic pain and major depressive disorder) by a number of medical practitioners and prescribed multiple medications. There was some misunderstanding and lack of knowledge about the prescription of certain medications from the patient's doctors. Two doctors did not know they both were prescribing oxycodone to the patient at the same time.

The Coroner concluded that the patient died from multiple causes including combined drug toxicity.

Coronial recommendation: That the Victorian DHHS commit to a timeline for the implementation of real-time prescription monitoring in Victoria, to reduce the harms and deaths associated with longstanding systemic health issues including poor co-ordination of care and inappropriate prescribing and dispensing.

Expected effectiveness of RTPM

The lack of co-ordination of treatment observed in this case would have been be minimised with RTPM, as it would been possible for the patient's medical specialist, general practitioner and pharmacist to be each made aware of the patient's medication supply history. RTPM reduces the harms and deaths from medication oversupply by enhancing clinical care between a patient's treatment team by facilitating information sharing and communication between health professionals.

Box 2.2: Case study – extract from 2014 Coronial inquest

2.2.1.2 Exemption settings with low risk of obtaining medicines beyond therapeutic need

In certain settings, such as aged care facilities, hospitals, prisons and police gaols, medicines are supplied or administered to patients under close supervision from medical professionals, and as such, patients are unlikely to be able to obtain medicines from multiple providers. Even if patients in these settings were able to access an inappropriate supply of medicines, in the event that an adverse event or overdose occurred, it is likely that medical help would be close at hand.

When use of SafeScript becomes mandatory, requiring healthcare professionals to check SafeScript before the prescription or supply of a monitored medicine in these settings could impose an unnecessary regulatory burden where the patient's prescription records are already known by those professionals, and there is limited potential for harm.

2.2.2 Ensuring proper operation of the system through regulations

In addition to identifying the sources of harm, the regulations are also necessary to specify:

- How SafeScript draws data from other systems and who will provide the data; and
- What information will be contained in SafeScript.

2.2.2.1 Data provision by prescribers and pharmacists

Currently, the requirement for a prescriber to include the date of birth of a patient on a prescription only applies for when issuing a prescription for Schedule 8 medicines. There is no current requirement for a pharmacist to record the date of birth when dispensing any prescription medicine.

The absence of the date of birth on a prescription record poses a problem for the effectiveness of SafeScript, since the date of birth is a key patient identifier that would enable the successful matching of patient records in SafeScript. The collection of these records is considered therefore essential to SafeScript to ensure that it meets its legislated objectives.

The proposed Regulations require that a prescriber who issues a prescription for a monitored poison must include the patient's date of birth on the prescription, and a pharmacist who supplies a monitored poison must include the date of birth in the record of supply to facilitate patient record matching.

2.2.2.2 Data provision by "data source entities"

The proposed regulations specify the data source entities that are required to provide prescription information to SafeScript. *Data source entities* are entities that are required to provide specified information to SafeScript. Without specifying what these entities are, there would be no requirement on the part of any entity to provide prescription records for the purposes of RTPM; while SafeScript would exist as legislated, it would contain no useful information due to there being no data transmitted into it.

Data source entities are considered an essential requirement to the system to ensure it meets its legislated objectives. The $29.5 million cost for the Victorian Government to establish SafeScript includes the cost of service agreements with data source entities to ensure that a secure, reliable and quality source of data is provided to SafeScript at all times.

The proposed Regulations specify Prescription Exchange Services (PESs) as the main data source entities. PESs are existing databases that facilitate communication between prescribing and dispensing software. These databases already collect much of the information needed for SafeScript, and so the system has been designed to interface directly with PESs to take advantage of the capabilities that already exist. An alternative data source entity considered in this RIS is obtaining data from pharmacists via direct integration with every dispensing software used in pharmacies, which is the approach taken in the Tasmanian RTPM implementation.

The records that data source entities are required to provide to SafeScript are also proposed in the Regulations. Without specifying which data records are required to be included in SafeScript, the database would not contain a sufficient level of information for healthcare professionals to make informed decisions about the safe and appropriate supply of a high-risk medicine.

3 Regulation design choices

This section identifies and considers the key design choices for the proposed Regulations that will enable them to meet their stated policy objectives.

3.1 Policy objectives and design choices

Overall, the main outcome that the Victorian Government aims to achieve through the legislation and the accompanying regulations is a reduction in harm caused by prescription medicines. This outcome is expected to be achieved through a reduction in episodes of multiple prescribing and a reduction in the oversupply of high-risk prescription medicines, resulting in a reduction in morbidity and mortality from prescription drug-related harms.

The proposed Regulations will support the objectives of RTPM by ensuring that SafeScript contains sufficient and suitable data records, specifying under what circumstances it should be used to be most effective, and ultimately enabling healthcare professionals to make informed prescribing and dispensing decisions.

Specifically, the proposed Regulations will:

(a) prescribe which entities are required to provide prescription records to the monitored poisons database;
(b) prescribe medicines which are to be included in the monitored poisons database;
(c) prescribe exceptions to the requirement to check the monitored poisons database; and
(d) prescribe the content of records to be provided to the monitored poisons database, where available.

3.2 Design choices

The two main design choices (or regulatory options) assessed in detail in Chapter 4 of this RIS are:

- Design Choice 1 – The selection of medicines to be monitored under SafeScript
- Design Choice 2 – The selection settings and circumstances under which it is not mandatory for health professionals to check SafeScript

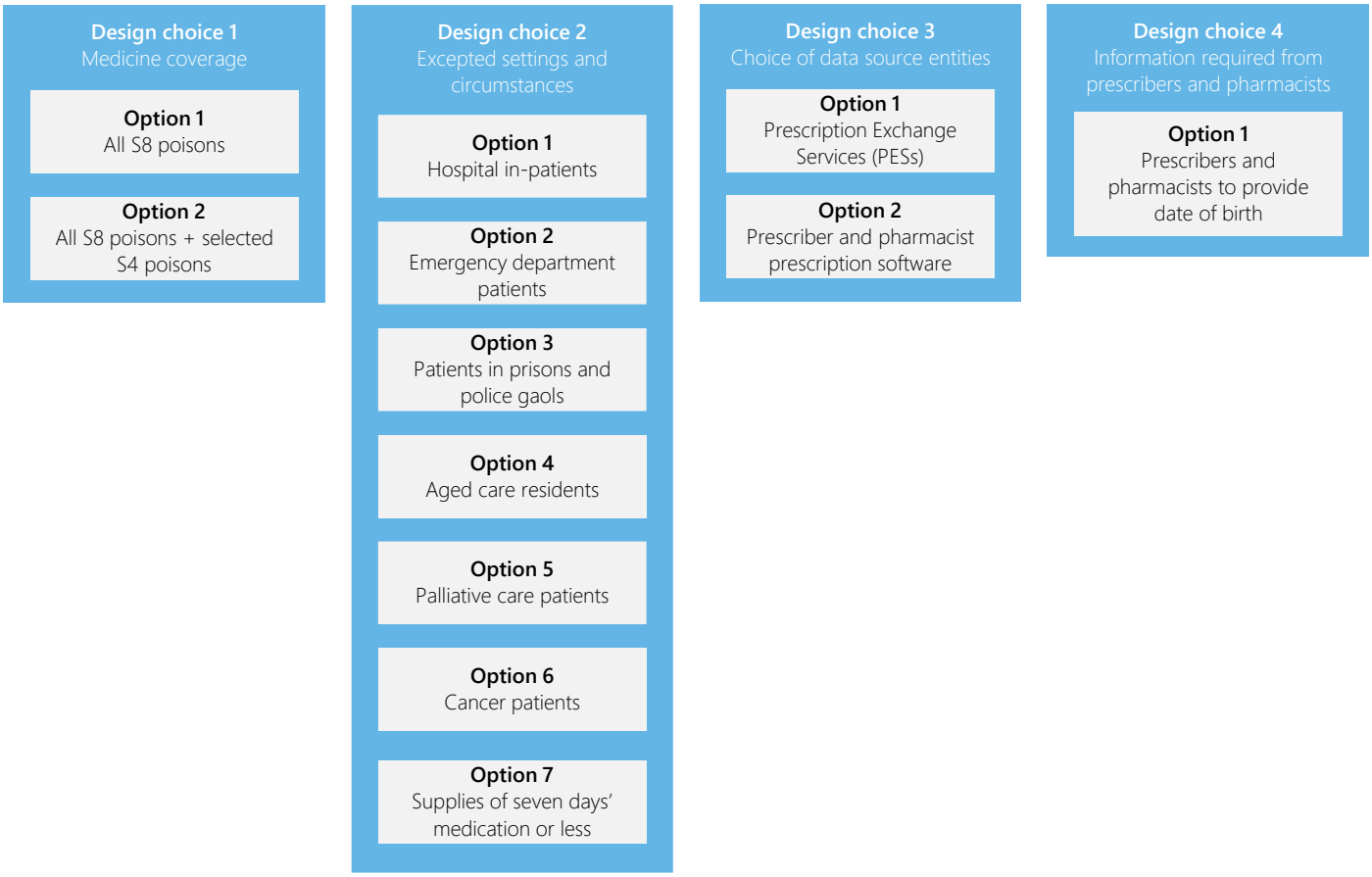
These are the two design choices within the Regulations that have the most significant impact on the expected costs and/or benefits of SafeScript. If appropriately selected, these design choices will ensure that SafeScript targets the medicines and settings where the benefits of regulation are greatest, and prevent unnecessary regulatory burden.

There are further design choices that are relevant to the technical implementation of SafeScript. These are:

- Design Choice 3 – The entities required by the Regulations to provide information to SafeScript
- Design Choice 4 – The information required to be provided to SafeScript for data matching purposes

The options presented and tested in this analysis have been developed in consultation with the External Advisory Group (EAG). A summary is shown in Figure 3.1.

Figure 3.1: A summary of the design choices, and the options within each design choice.



3.3 Design Choice 1 - Medicine coverage

The first regulation design choice assessed in this RIS relates to the range of medicines to be designated as *monitored supply poisons* (and for which SafeScript must be consulted before prescriptions are issued or dispensed) when use of SafeScript becomes mandatory from 1 April 2020.

Option 1: All S8 poisons to be monitored supply poisons

The Act specifies that at a minimum, all S8 poisons will be *monitored poisons*. This is appropriate, given that S8 poisons carry the greatest risk of harm and additional controls are in place on their use and supply, including requirements for prescribers to obtain a permit when treating patients with S8 poisons. Removing the existing permit system entirely was not considered by DHHS to be aligned with the objectives of SafeScript. This means that the S8 permit system and SafeScript will operate in parallel to provide oversight in the safe prescribing and supply of high-risk medicines in Victoria.

The *Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Bill 2017* (passed in October 2017), contains amendments that would allow DHHS to streamline a number of existing Schedule 8 permit and notification requirements for prescribers that either relate to low risk circumstances, or through the advent of SafeScript, would result in duplicative processes and create unnecessary regulatory burden.

These changes include:

- Removing permit requirements when prescribing an opioid at a dose less than 100mg daily in morphine equivalent dose
- Removing notification requirements when prescribing an opioid for cancer pain
- Removing permit/notification requirements for psychiatrists prescribing a psychostimulant for ADHD
- Removing notification requirements for paediatricians prescribing a psychostimulant for childhood ADHD
- Removing notification requirements when treating a drug-dependent person.

The streamlined changes to the S8 permit requirements will apply in circumstances where prescribers check SafeScript before prescribing a Schedule 8 poison. That is, the streamlined changes will only apply to prescribers who elect to use SafeScript during the initial transition period, and will take effect for all prescribers when use of SafeScript becomes mandatory. The delivery of training for prescribers and pharmacists as part of the implementation of SafeScript will include a module on the regulatory obligations associated with the streamlined changes to the S8 permit system,

This streamlining of the S8 permit system is expected to reduce any duplication between the two systems, and also reduce the regulatory burden on prescribers by reducing the amount of information they are required to provide to DHHS. At the same time, in order to avoid reduced effectiveness in reaching the objectives of the S8 permit system, all S8 poisons are specified as *monitored poisons*. For the purposes of the RIS, this is considered the minimum coverage of medicines outside of the base case, as it reflects what additional controls are already in place.

Option 2: All S8 poisons and selected S4 poisons to be monitored supply poisons

There are other, non-S8 prescription medicines that cause significant harm in Victoria. In 2017, the Victorian Government commissioned Austin Health to develop an evidence base into which other medicines should be monitored by SafeScript. The literature review, titled 'Evidence to inform the inclusion of Schedule 4 prescription medications on a real-time prescription monitoring system' (Austin Health, 2017), identified a number of S4 poisons in Australia and internationally with definite and concerning trends in misuse, and overdose.

The Austin Health literature review includes extensive quantitative and qualitative analysis of S4 poisons and their potential for harm within a local context. The local use of high-risk prescription medications vary to a degree with international comparisons depending on local context. For example, there is a lower incidence of misuse of codeine in North America due to the availability of more accessible alternatives such as hydrocodone. It is noted in the literature review that the most

effective prescription monitoring systems around the globe regularly adjust and adapt their systems to suit local need and trends over time.

The EAG considered the research and information contained in the Austin Health literature review, including:

- the risk of harm associated with individual medicines,
- the risk of harm associated with classes of medicines,
- potential drug trends; and
- drugs included in prescription monitoring systems in the United States (as monitoring systems are well-established in the United States, with 49 out of 50 states having a system in operation).

Based on the findings of the literature review, the External Advisory Group recommended that in addition to all S8 poisons, the following Schedule 4 medicines should be specified as monitored supply poisons.

Option 2 considers the inclusion of these S4 poisons, in addition to all S8 poisons (Austin Health, 2017):

- All benzodiazepines (bromazepam, clobazam, clonazepam, diazepam, lorazepam, midazolam, nitrazepam, oxazepam, temazepam) - Peer-reviewed literature indicates that benzodiazepines contribute to a significant proportion of harm caused by prescription medicines. When combined with opioids or opioid replacement therapy, benzodiazepines pose a serious risk of harm leading to overdose. As a class of medicines, benzodiazepines are highly susceptible to substitution. This means that if some patients were restricted access to some (but not all) benzodiazepines, then they would likely obtain those other benzodiazepines that were more accessible. Therefore, monitoring only selected benzodiazepines would likely result in a shift in the risk of serious harm from one substance to another.
- Z-drugs (zolpidem, zopiclone) - Like benzodiazepines, these medicines are used for their sedative and hypnotic effects.. According to the Austin Health literature review, this class of medicines appears culpable for a significant burden of harm. The two main Z-drugs (zopiclone and zolpidem) are considered substitutable, meaning that there is a high risk that one medication could be substituted for the other in the case that both are not monitored.
- Quetiapine (an antipsychotic) -Evidence supports the inclusion of quetiapine in RTPM but does not support other antipsychotics (such as olanzapine and risperidone), which have been shown not to contribute to as great a burden of harm. According to the Austin Health review, quetiapine has "possibly demonstrated the most concerning trend of all the antipsychotics in recent years". At the same time, limited substitution medicines were identified, due to differences in the rewards pathways between quetiapine and other antipsychotics, implying that addiction to quetiapine is less likely to transfer to other antipsychotics.
- All combination analgesics containing codeine - Codeine containing analgesics have sufficient harm associated with them to be monitored, particularly given the proportion of over-the-counter combination products that contribute to liver failure, severe gastrointestinal ulceration and addiction. The timing surrounding the introduction of (currently) over-the-counter codeine containing analgesics to RTPM will be specially considered in respect to their up-scheduling to Schedule 4 in February 2018. Considering the impact of up-

scheduling, the EAG recommended delaying the inclusion of codeine in SafeScript to a later stage of implementation.

There were a number of S4 medications which were also reviewed in this category, but were ultimately considered to be not sufficiently high-risk in comparison to the medicines included in SafeScript to justify their inclusion as medicines to be monitored (Austin Health, 2017):

- Gabapentin and pregabalin are anticonvulsants, the use of which has escalated rapidly at the global level. However, there is limited evidence of harm in Australian peer-reviewed literature. While these medicines may pose a future threat, proportional rates of death in this cohort were relatively small.
- Tramadol is a prescription opioid. Like gabapentin, there was some global evidence to suggest that tramadol causes harm, but evidence suggested that it was less commonly misused in Australia. Based on its existing prescription levels, it also has a notably lower rate of toxicity than the highest-risk S4 medicines.

While, these medicines will not be monitored at the commencement of SafeScript, the process of determining the scope of medicines monitored in SafeScript is dynamic. The proposed Regulations will enable either other S4 medicines to be included in the future should additional medicines emerge as causing significant risk of harm to the community or currently monitored S4 medicines to be removed. There is also scope in future to specify additional S4 medicines as *monitored poisons* only, and not as *monitored supply poisons*, meaning that such S4 medicines would be included in SafeScript, but it would not be a mandatory requirement for health practitioners to check SafeScript before prescribing or supplying such S4 medicines.

3.4 Design Choice 2 – Excepted conditions and circumstances

The second design choice assessed in detail in this RIS relates to the selection of settings and circumstances where health professionals are not required to check SafeScript when use of the system becomes mandatory. The purpose of allowing exceptions is primarily to minimise regulatory burden. Where settings of low risk are identified, exempting these from monitoring would not be expected to be at odds with the objectives of the legislation to promote safe supply and reduce harm.

The impact of providing exceptions in these selected settings and circumstances are considered qualitatively in the following chapter.

Options 1-4: Closed settings

The legislation and proposed Regulations aim to reduce harmful use of high-risk prescription medicines through both a reduction in episodes of multiple prescribing and a reduction in the oversupply of high-risk prescription medicines. This infers that, for a setting to be suitable for exception from the mandatory use of SafeScript, it must be one in which a patient's ability to obtain supplies beyond therapeutic need or misuse of medicines is limited, including that there is a record of the medicines administered to the patient (at least while they have been in that setting) available to all health professionals treating the patient.

The settings in the proposed Regulations are:

- **Option 1:** An in-patient being treated in a hospital;

- **Option 2:** A patient being treated in an emergency department of a hospital;
- **Option 3:** A patient being treated in a prison or police gaol;
- **Option 4:** A resident being treated in an aged care service.

Note that the exception from checking SafeScript in relation to a hospital in-patient or emergency department patient would not apply where the patient is prescribed or supplied a monitored supply poison on discharge.

All these settings constrain the ability for the patient to access additional medicines because of the confined nature of the clinical setting and therefore decreased mobility of patients. They all also constrain the potential for misuse of or overdose from medications through their supervised administration, usually by medical or nursing staff. These settings for which exceptions from mandatory use of SafeScript are being proposed include most of the same settings where the legislation currently provides for exceptions for prescribers from S8 permit requirements.

Option 5: Palliative care patients
Another option considered would provide exceptions from the mandatory use of SafeScript where the following applies:

(a) the person is suffering an incurable, progressive, far-advanced disease or medical condition; and
(b) the prognosis is of limited life expectancy due to the disease or medical condition; and
(c) the supply of the monitored supply poison is intended to provide palliative treatment; and
(d) the person is not a drug-dependent person.

These circumstances have been chosen because they cover palliative care patients who would be likely to require increased or more frequent supplies of monitored poisons as a part of genuine clinical need or progression of their illness.

Under this option - in cases where the above four conditions are known to a patient's prescriber or pharmacist, then there would be no requirement to check SafeScript. However, if prescribers or pharmacists are not aware whether these conditions apply, or if the patient that is receiving palliative care for a terminal illness is exhibiting aberrant drug-related behaviours which indicates drug dependency (such as drug-seeking, escalating dose without or against medical advice, or suspicion of diversion or sharing of medicines) then the prescriber or pharmacist would be required to check SafeScript.

Option 6: Cancer patients
Given that the legislation already provides for S8 permit exceptions in certain circumstances, such as when treating a patient with cancer pain, an exception from mandatory use of SafeScript when treating patients with cancer pain was also considered.

Option 7: Supply of seven days' medication or less
Another option considered by DHHS was to provide an exception from mandatory use of SafeScript where the duration of the prescription was less than one week. This exception is in place in some mandated prescription drug monitoring programs in the United States, as short supply periods by themselves may be considered generally not sufficient to lead to drug-dependency.

3.5 Design Choice 3 – The choice of data source entities

While SafeScript is established by the legislation, the choice of data source entities - which provide information on prescription medications to the database - is specified in the Regulations. Two possible options for Victorian implementation exist at present.

Option 1: Prescription Exchange Services

The first option is to specify Prescription Exchange Services (PESs) as the main class of data source entity to provide prescription data to SafeScript. PESs are existing databases that interact with prescribing and dispensing software used by prescribers and pharmacists to facilitate the communication and verification of electronically created prescriptions.

Option 2: Prescriber and pharmacist prescription software

The other option is for SafeScript to interface directly with software that is used by prescribers and pharmacists to create and dispense prescriptions. This approach is used by the Tasmanian RTPM implementation, which obtains data from pharmacists by integrating with dispensing software used in pharmacies.

3.6 Design Choice 4 – Information required from prescribers and pharmacists for data-matching purposes

To facilitate the matching of records within SafeScript, some personal information must be collected from patients. While the Medicare number would be useful for data matching purposes, the Privacy Guidelines for the Medicare Benefits and Pharmaceutical Benefits Programs, issued under section 135AA of the *National Health Act 1953*, limits prescribers and pharmacists from using the Medicare number or purposes other than for the supply of a medical or pharmaceutical benefit under the MBS and PBS.

Other possible unique identifiers, such as driver's licence number, are not held by the entire population. Further, other pieces of patient information which could be used for linkage purposes, such as current address, are not fixed, and so can hamper the ability to track patients through time.

Therefore, DHHS considers the option of requiring the collection of a patient's date of birth is appropriate, which can be combined with patient names and other stored information to accurately and reliably identify and match patient records.

4 Options analysis

This section of the RIS analyses the design choices (also described as 'options') for the proposed Regulations to determine a preferred approach.

4.1 Analysis framework

As outlined in Chapter 3, the design choices considered in the options analysis are:

- **Design Choice 1 –** the selection of medicines to be monitored by SafeScript
- **Design Choice 2 –** the selection of settings and circumstances under which it is not mandatory for health professionals to check SafeScript
- **Design Choice 3 –** the entities required by the Regulations to provide information to SafeScript
- **Design Choice 4 –** the information required to be provided for data matching purposes

While Design Choices 1 and 2 are important in determining how well SafeScript meets its objective of targeting harmful medicines, Design Choices 3 and 4 are crucial for ensuring that the system operates effectively and efficiently.

The approach taken for this RIS is to assess the design choices in a sequential manner. The options for Design Choice 1 have been assessed using a cost-benefit analysis. Once the preferred option for medicines is established, it is treated as given, and the options for Design Choices 2-4 are each assessed separately using a qualitative approach.

There is expected to be limited interaction between Design Choices 2-4 (and between these and Design Choice 1), and as such, DHHS considers it is reasonable to assess each separately.

4.2 Design Choice 1 – Medicines coverage: cost-benefit analysis

The proposed Regulations state which medicines are to be monitored by SafeScript. As such, it is important to consider the impacts imposed by monitoring the different medicines or classes of medicines.

The RIS considers three cases of medicines coverage – a base case, and two scenarios. These are:

- **Base case:** the base case for the analysis is a situation where there is no RTPM. This is because RTPM relies on *monitored supply poisons* to be specified in the regulations in order to function.
- **Option 1:** monitored supply poisons to include all S8 poisons listed in Table 4.1.
- **Option 2:** monitored supply poisons to include all S8 poisons, as well as a number of Schedule 4 poisons causing significant harm in the community listed in Table 4.1.

Table 4.1: S8 and S4 poisons to be monitored by SafeScript

S8 poisons	S4 poisons
Alprazolam	Bromazepam
Buprenorphine	Clobazam*
Codeine (S8 only)	Clonazepam
Dexamphetamine	Diazepam
Fentanyl	Lorazepam*
Flunitrazepam	Midazolam*
Hydromorphone	Nitrazepam
Ketamine*	Oxazepam
Lisdexamfetamine	Quetiapine
Methadone	Temazepam
Methylphenidate	Zolpidem*
Morphine	Zopiclone
Nabiximols*	
Oxycodone	
Pethidine*	
Tapentadol	

* These medicines are not listed on the PBS, and so prescription numbers are unavailable. However, these medicines (aside from zolpidem) are less commonly prescribed than medicines that are listed on the PBS, and hence are not expected to significantly affect the modelling results.

Note: The S8 poisons and S4 benzodiazepines listed in this table are those that are currently available and registered for therapeutic use in Australia. However, the proposed Regulations prescribe 'All Schedule 8 poisons' and 'All benzodiazepines that are Schedule 4 poisons'. Therefore, the specific medicines included in SafeScript will automatically change if there are changes to the poisons included as S8 poisons and/or S4 benzodiazepines.

Table 4.2 summarises the costs and benefits considered for both options.

Table 4.2: Summary of the costs and benefits considered in the cost-benefit analysis of medicines coverage

Key Costs	Key Benefits
Fixed and ongoing implementation, compliance monitoring and enforcement costs	Social benefit of saved lives
Time-costs of training and registration	Savings from reduced hospital admissions
Time-cost of checking a patient record in SafeScript	Savings from reduced emergency department presentations
Cost of intervention	Savings to the PBS from fewer prescriptions being dispensed

4.2.1 Costs

4.2.1.1 Fixed and ongoing implementation, compliance monitoring and enforcement costs

In the 2016-2017 State Budget, the Victorian Government allocated $29.5 million over four years towards the implementation of SafeScript. This cost includes implementation of the software solution, including its roll out to medical clinics, pharmacies and hospitals around the state, as well as resources for training prescribers and pharmacists.

This $29.5 million cost is included in the cost-benefit analysis for the purposes of comparing it to the base case where there is no RTPM implemented.

Ongoing costs of $2.8 million per year are expected to be required to maintain the system into the future. This includes costs for maintenance and upgrades to SafeScript, as well as costs involved with auditing the use of the system and ensuring compliance.

4.2.1.2 Time-costs of training and registration

The Victorian Government's $29.5 million allocation towards SafeScript includes funding towards health workforce development. This will take the form of resources to train prescribers and pharmacists in using SafeScript, as well as registering them on the database.

Despite this funding, there is still likely to be a regulatory burden stemming from training and registration in the form of an opportunity cost borne by prescribers and pharmacists, as they will need to allocate time for training and registration activities. This time has been minimised by the Government's chosen approach, which is to make available registration and training online. As such, this minimises the lost time (due to travel) to training facilities that may have otherwise been required.

This opportunity cost has been captured in the cost-benefit analysis by taking the number of prescribers and pharmacists new to SafeScript in each year (which will

be all existing prescribers and pharmacists in the first year), and calculating the wage they could have earned in the time it takes to train and register.

The training and registration costs are fixed between the two options medicine coverage options considered in the analysis. This is because the training and registration predominantly relates to proper use of the software solution, and as such would not be substantially different depending on the underlying medicines that require monitoring.

4.2.1.3 Time-cost of checking a patient record in SafeScript

One of the main regulatory burdens stemming from SafeScript is the time cost it imposes when a prescriber or pharmacist is considering the prescription or dispensing of a prescription medicine. This is an opportunity cost that has been captured by calculating the wage cost of this checking time. This does not mean that the prescriber or pharmacist is paid less for the time they work, but rather reflects the value of their labour that could have otherwise been directed towards other tasks.

While there is a time impost on checking a patient's medication history, health professionals have existing legal and professional requirements to take all reasonable steps to ensure a therapeutic need exists before prescribing a medicine and to ensure that the supply of a medicine is consistent with the safety of the patient. For example, prescribers who have been requested by a patient new to their clinic to prescribe a high-risk medicine, are expected to verify the patient's medication history before deciding the appropriateness of treatment. Current sources available to health professionals to gather information on a patient's medication history include contacting the Medicare Australia Prescription Shopping Information Service, the Drugs and Poisons Regulation information service, information available from My Health Record, or by contacting the patient's previous prescribers and pharmacists. However, in all these sources, information is incomplete, not in real-time, and often burdensome to obtain. Evidence that the amount of harm caused by high-risk prescription medicines is increasing and that it often occurs when patients obtain supplies beyond therapeutic need from multiple prescribers, suggests that these obligations are not always able to be effectively fulfilled by all health professionals.

DHHS considers that SafeScript would be a more efficient mechanism for fulfilling a health professional's obligations to verify a patient's medication history before prescribing or supply a medicine for patient safety, as SafeScript would provide a more complete set of information without needing to contact multiple sources to collect this information. Rather than be only considered as a time burden, SafeScript would optimise the time allocated within a medical appointment towards patient-facing activities such as patient assessment and counselling, rather than on information history gathering activities.

For both prescribers and pharmacists, the checking time is assumed to be one minute. Although the actual time it will take is not known at this stage (because SafeScript currently under development), DHHS considers this is an upper bound estimate. DHHS is cognisant of the need to ensure access for clinicians to view patient records in SafeScript is as seamless as possible. A key issue in this regard appears to be software integration - prescribers in the US, for example, were initially reluctant to use prescription monitoring systems because they were not integrated with clinical workflow, so integration is now progressively being

introduced in the US to increase uptake. The Commonwealth software does not provide for integration with existing clinical practice systems to access patient records, so Victoria is seeking to avoid the issues that arose in the US by developing bespoke software that will meet the needs of clinicians by providing integration at the start of implementation. SafeScript is designed to impose minimal impact on existing clinical workflows, hence a more likely duration for checking would be counted in seconds rather than minutes. This is because, in most cases, SafeScript will provide prescribers and pharmacists with pop-up notifications in real-time to provide information on whether records relating to a patient exists within SafeScript and requires further investigation, and that the patient history can be accessed through an integrated link contained in the pop-up notification within seconds.

Prescribers and pharmacists both have a duty of care to ensure the supply of medicines is safe and appropriate for a patient. Hence, it is expected that prior to every prescribing or dispensing event, SafeScript would be checked by both a prescriber and pharmacist, so that each can make the appropriate clinical decision based on information in the database. For the purposes of the RIS, events where the supply is considered to be within therapeutic need are referred to as "appropriate prescriptions". However, there will be situations where a prescriber has checked SafeScript, and considers issuing a further prescription to be inappropriate. For the purposes of the RIS, these events are referred to as "inappropriate prescriptions". Given that a prescription is not issued, in these situations the pharmacist does not check SafeScript since no prescription has been presented to the pharmacist. As such, the cost-benefit analysis takes into account the fact that pharmacists would not be required to check SafeScript when prescribers have deemed that it would be inappropriate to prescribe the medicine.

While this approach does not explicitly model repeat prescriptions where the pharmacist would be expected to check prescriptions more often than the prescriber, the checking cost is tied to the time taken to check each prescription, which is included in the sensitivity analysis. Such an approach is taken due to the lack of data on repeat prescriptions. The sensitivity analysis takes into account this uncertainty by modelling a highly conservative case where the costs of checking SafeScript are increased from 1 minute to 3 minutes. Even with this variation in the time taken to check SafeScript, the analysis suggests that SafeScript still provides a net benefit.

The checking cost was calculated separately for "appropriate" and "inappropriate prescriptions". For "appropriate prescriptions", the time taken to check SafeScript by prescribers and pharmacists was combined with their respective wages to serve as a proxy for capturing the "opportunity cost" of checking SafeScript: that is, the cost associated with foregoing other activities, such as treating patients or performing administrative activities. This was applied to every "appropriate prescription" twice: once for the prescriber, and once for the pharmacist. For "inappropriate prescriptions", the same method was used, except that fewer pharmacists were required to check prescriptions, owing to the expectation that prescribers would no longer prescribe at the same volume due to prescribers providing fewer prescriptions to patients who are obtaining supplies beyond therapeutic need.

4.2.1.4 Cost of intervention

The purpose of SafeScript is to enable clinicians to make more informed clinical decisions when considering the prescribing or supply of a prescription medicine to a patient. In the case of patients who exhibit signs of dependency on a high-risk medicine, this will enable clinicians to make a clinical intervention or recommend alternative treatments to address such dependencies. While this intervention has benefits insofar as it reduces peoples' dependencies on prescription medicines, there are also costs associated with undertaking this intervention. This includes consideration of the time and financial costs for health professionals providing counselling, education and professional advice, as well as the course of treatment within an AOD service for conditions such as opioid dependency. Patients may also access AOD services for further counselling or withdrawal and drug rehabilitation services.

The weighted average cost of each intervention, involving treatment in either a primary care or AOD service setting, is assumed to be $1,205 per patient. For the purposes of the cost-benefit analysis, it is assumed that 25% of patients who are identified as obtaining supplies of medicines beyond therapeutic need receive treatment through AOD services, and the remaining 75% receive treatment from a GP[2]. For patients receiving treatment through AOD services, the cost was calculated based on the average cost for a course of treatment, multiplied by the average number of courses of treatment per patient[3]. For patients receiving treatment from GPs, the cost was calculated based on patient receiving an extended consultation of over 40 minutes.

To more accurately calculate the overall cost of intervention over the 10-year period in the analysis, it is important to consider how the number of patients requiring intervention changes over time after SafeScript is implemented.

In Ohio, USA, the rate of multiple provider episodes identified (where patients were visiting five or more prescribers and five or more pharmacies within three months) fell by 42% in 2015 after the use of a prescription drug monitoring program was mandated, relative to levels observed in 2011 prior to the program's introduction (The Pew Charitable Trusts, 2016). There are other examples of this impact in the US, however the reduction experienced in Ohio is the most conservative benchmark, noting that it is difficult to predict what will occur in Victoria[4]. The

What is the "Value of Statistical Life"?

When attempting to quantify the impact of a policy or regulation, sometimes it becomes necessary to compare monetary costs and benefits to the costs and benefits of intangible things, such as the life itself. The value of statistical life (VSL) provides a way to make this comparison. The VSL reflects the financial value that society places on reducing the average number of deaths by one.

In Australia, the standard VSL life used for cost-benefit analyses is $4.2 million in 2014 dollars, assuming 40 years of additional life, as defined by the Office of Best Practice Regulation (OBPR, 2014). However, international studies have shown that the VSL may vary from between $3 million and $15 million, so this should be taken into account when making assessments relying on the VSL.

Box 4.1: The Value of Statistical Life

[2] There is limited evidence available to indicate the proportion of patients that will seek treatment from AOD services. A report (National Drug and Alcohol Research Centre, 2014) estimated that approximately 25% of people with substance use disorders accessed AOD services in 2007. The remaining 75% of patients have been assumed to receive treatment in primary care, in the form of a GP consultation over 40 minutes (MBS Item 44). This is likely to be a conservative estimate, because the 25% includes people seeking treatment for alcohol and other substances including cannabis. Patients seeking help for dependence on prescription medicines will be more likely to engage with their primary care health provider because of the stigma associated with accessing alcohol and drug services, which are traditionally orientated towards illicit drug use.

[3] The average cost for a course of treatment in AOD services for 2016-17 was $2,383. The average number of courses of treatment per unique client was 1.93. This takes a range of complexity of services into account including patients accessing basic counselling through to residential rehabilitation services.

[4] 42% is a lower-bound estimate from the US. In New York, the observed reduction in the number of individuals involved in multiple prescriber episodes (defined in this case as five or more prescribers and five or more pharmacies within one month) fell by 91% after three full years of a system becoming mandated. In Kentucky, the observed reduction in multiple provider episodes (four or more prescribers and four or more pharmacies within a three-month period) after 1 year of the system being mandated

number of patients identified as obtaining supplies of medicine beyond therapeutic need is Victoria is therefore assumed to have a stepped-reduction of 42% between 2020-21 (when the system becomes mandatory) and 2021-22, and remain constant thereafter. This provides evidence to suggest that SafeScript will be effective in allowing prescribers and pharmacists to identify patients before requiring treatment for dependency, as well as the ongoing preventative effect that SafeScript will have to this end.

4.2.2 Benefits

4.2.2.1 Social benefit of lives saved

The largest benefit by far in the cost-benefit analysis is the social benefit of lives saved by SafeScript. This is due to the value placed on each additional life saved (see Box 4.1): the standard value used for cost-benefit analyses in Australia is $4.2 million in 2014 dollars (OBPR, 2014), which equates to approximately $4.5 million in 2017 dollars.

As the value of each additional life saved is relatively high, the results of the analysis are very sensitive to this, and so the model makes conservative estimates regarding the ability of SafeScript to save lives.

The number of overdose deaths for which monitored S4 and S8 poisons were a contributing factor was drawn from a report from the Victorian Coroner (Dwyer, 2016). In 2016, the most recent year for which data is available, the ratio of the number of deaths caused by overdose where selected S4 poisons (including only those listed in Table 4.1) were a contributing drug, to the number where S8s were a contributing drug, was approximately 2:1. Therefore, for modelling purposes, the share of deaths caused by S4 poisons was estimated to be 67%, and the share caused by S8 poisons was 33%.[5]

A crucial factor in determining the number of lives saved is the effectiveness of SafeScript. Since the introduction of RTPM in Tasmania, the state has experienced a 5% reduction in the number of deaths (PBAC, 2015). However, given that the Tasmanian system is based on voluntary use by prescribers, its effectiveness is expected to be less in comparison to jurisdictions where use of the system is mandatory. In addition, the Tasmanian system only covers S8 poisons, whereas one of the proposed options for SafeScript covers selected harmful S4 poisons in addition to S8 poisons. As such, it was considered more appropriate to draw on evidence from the US which showed state-based mandatory prescription monitoring systems have reduced deaths by 12% (Dowell, Zhang, Noonan, & Hockenberry, 2016). It is noted that data from the US context may lack validity in Australia, where the health system is very different. However, in the absence of comparable information available in Australia, the US estimates have been used for

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was 52%. We have used this figure from Ohio because it is most conservative out of the examples, and its definition of multiple provider episodes is most closely aligned to Victoria's.

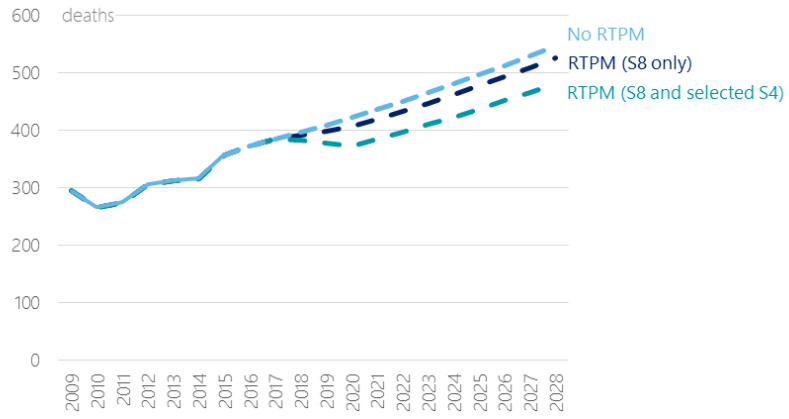
[5] In 2016, selected S4 poisons (including only those listed in Table 4.1) were a contributing drug in 378 deaths, while S8 poisons were a contributing drug in 183 deaths, totalling 561 deaths. Note that this figure is greater than the number of actual deaths from prescription medicine misuse or overdose in 2016, which was 372, because each death may involve more than one contributing drug. For modelling purposes, (i) the number of deaths with or without RTPM is based on projections from the 372 deaths recorded in 2016 and (ii) the share of deaths caused by S4 poisons was chosen as 378/561 = 67%, and the share caused by S8 poisons was chosen as 183/561 = 33%.

modelling purposes. A lower (5%) reduction in deaths caused by SafeScript - the Tasmanian figure - was considered in the sensitivity analysis.

For the transitional period before use of the system becomes mandatory, it is assumed that the uptake rate will be 4% (as occurred in Tasmania) with the anticipated reduction in deaths being 3.5%. This figure of 3.5% is less than occurred in Tasmania (5%) because the Tasmanian Department of Health and Human Services exhaustively tracks in real-time the dispensing of S8 medicines per transaction and immediately follows up breaches with the practitioners involved. DHHS considers that the regulatory approach in Tasmania could not be replicated in Victoria. On a population basis SafeScript will capture approximately ten times the number of transactions that are processed through the Tasmanian system and implementing the Tasmanian surveillance approach in Victoria will not be scalable in the Victorian context. This level of oversight would also not be consistent with enabling clinicians to make their own autonomous decisions about the supply of medicines monitored through the system based on best evidence and information of previous supply. Hence, a lower assumption around deaths avoided has been adopted during the transitional period.

Deaths occurring due to prescription medicines were projected using the current trend observed in data from the Coroner's Prevention Unit (2017). Figure 4.1 shows the difference in deaths modelled.

Figure 4.1: Projected deaths in Victoria with and without RTPM



Source: Coroner's Prevention Unit (2017) – historical information

4.2.2.2 Savings from reduced hospital admissions

The Centers for Disease Control and Prevention (CDC), a unit within the United States Department of Health and Human Services, has published research considering the impact of opioid misuse and overdose on the healthcare system. The CDC estimated that for every overdose death from prescription painkillers there are 10 treatment admissions for prescription medication misuse (see Box 4.2). There are some qualifications that mean this ratio may not hold exactly in Victoria for RTPM. In particular, the list of medicines to be monitored in SafeScript will not exclusively contain opioid analgesics (which the CDC considered), and there are differences between the Australian and US health systems which may impact on the rate at which patients are hospitalised. However, despite these limitations, there is a lack of Australian data (or international data ranging across these various

Noting that overdose deaths have increased substantially in the United States over the past decade, the CDC conducted research to consider the broader impacts of misuse of or overdose on prescription painkiller medication.

The research indicated that for every overdose death from prescription painkillers there are:

- 10 treatment admissions for abuse; and
- 32 emergency department visits for misuse or overdose
- 130 people who abuse or are dependent on prescription medications
- 825 people who take prescription painkillers for non-medical use.

Box 4.2: CDC findings on the relationship between prescription medicine deaths and other adverse events (Centers for Disease Control and

Medicare Australia's Prescription Shopping Program, sponsored by the Commonwealth Department of Human Services (DHS) defines prescription shopping as:

Where a person, within any threemonth period, has had supplied to them

- PBS items prescribed by 6 or more different doctors, and/or
- more than a specified number (25) of target items under the PBS, including analgesics, antiepileptics, anti-Parkinson's medicines, psycholeptics, psychoanaleptics (including antidepressants) and all other nervous system medicines, and/or
- a total of 50 or more PBS items.

This implies that for every person identified as prescription shopping in a given calendar year there are a minimum of 24 GP visits and a minimum of 100 PBS prescriptions filled for target PBS items.

Box 4.3: DHS's definition of prescription shopping (Department of Human Services, 2017)

classes of prescription medications) with which to base alternative estimates. As such, the number of hospitalisations varies in the model in accordance with this fixed ratio against the reduction in deaths. The cost of admission was based on the national efficient prices (NEP)[6] for a set of relevant Australian Refined Diagnosis Related Groups (AR-DRGs). AR-DRGs are part of a system commonly used to classify patients in acute hospitals. The price of a hospital admission was estimated as the efficient price for the following AR-DRGs:

- V61Z – Drug Intoxication and Withdrawal;
- V63Z – Opioid Use Disorder and Dependence; and
- V64Z – Other Drug Use Disorder and Dependence.

The cost weight for each of these AR-DRGs was based on the number of separations reported in the Australian Public Hospitals Cost Report 2013-2014 (Independent Hospital Pricing Authority, 2016a). These weights were multiplied by the NEP for 2016-17 (Independent Hospital Pricing Authority, 2016b).

Using these calculations, the cost of each hospital admission used for modelling purposes was $7,739.51 in 2017 dollars.

4.2.2.3 Savings from reduced emergency department presentations

The CDC study has also been used to define a fixed ratio of 32 emergency department (ED) presentations per overdose death (see Box 4.2). The cost of ED presentations is estimated based on a set of relevant Urgency Disposition Groups (UDGs). UDGs are a standardised way to classify patients in EDs and group presentations according to type of visit, episode end status and triage. The relevant UDG codes used to estimate the cost included the following:

- 15 – Admitted Triage 2 – Toxic effect of drugs;
- 25 – Admitted Triage 3 – Poisoning/Toxic effects of drugs;
- 30 – Admitted Triage 4 – Poisoning/Toxic effects of drugs; and
- 40 – Non-Admitted Triage 2 – Alcohol/drug abuse.

Specifically, the price weights for each of these UDGs were averaged and multiplied by the NEP for 2016-17 to arrive at an expected price per ED visit (Independent Hospital Pricing Authority, 2016c).

Using these calculations, the average cost of each emergency department presentation was $895.91 in 2017 dollars.

4.2.3 Modelling approach

4.2.3.1 Prescription volumes and prices

To separate out the effects of monitoring S8 poisons only versus S8 and S4 poisons, the modelling approach projected the number of prescriptions and cost of prescriptions separately for each group of drugs. These projections were calculated using an average of growth rates in previous years and are shown in

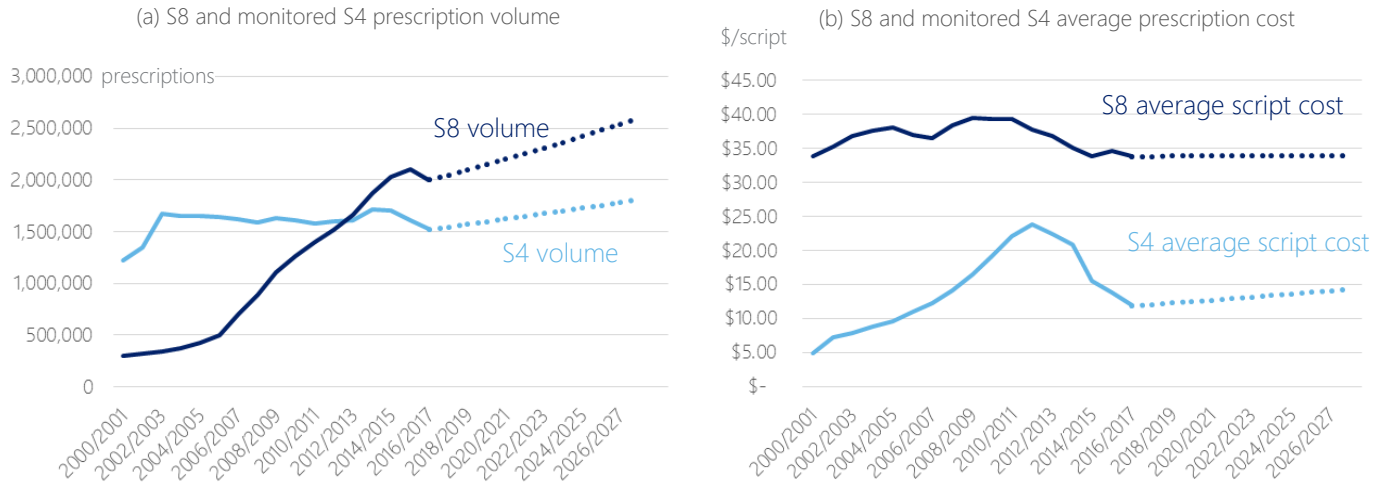
Figure 4.2.

[6] The National Efficient Price (NEP) is the price the Government pays per unit of activity for hospital services that are funded by activity level.

It is important to note that any projected prescription volumes and prices are very sensitive to future policy decisions. For example, rescheduling or delisting decisions may affect the quantity of medicines in either schedule, or their presence in the PBS. For the purposes of this analysis, a linear trend has been assumed, calculated using an average growth rate over several years of previous growth. The number of years used to calculate the projected growth is variant between series, due to the presence of structural breaks, such as in the S4 average prescription cost, which peaked in 2011/12.

Figure 4.2: Historical data and projections for monitored medicines Victorian PBS prescription volumes and prices.

Note: Projections are shown as the dotted trend lines. These were calculated using an average of past growth rates.



Source: PBS

4.2.3.2 A note on the compliance assumption

While the cost component of the modelling assumes high levels of compliance (every patient obtaining supplies beyond therapeutic need is identified and provided with treatment), this is not reflected in the benefits as these are calculated using United States prescription monitoring system implementations, where 100% compliance may not necessarily be assumed. As such, the modelling overstates the costs of compliance, but not necessarily the benefits. This approach was taken in order to be conservative about the net return of SafeScript.

4.2.3.3 Modelling methodology

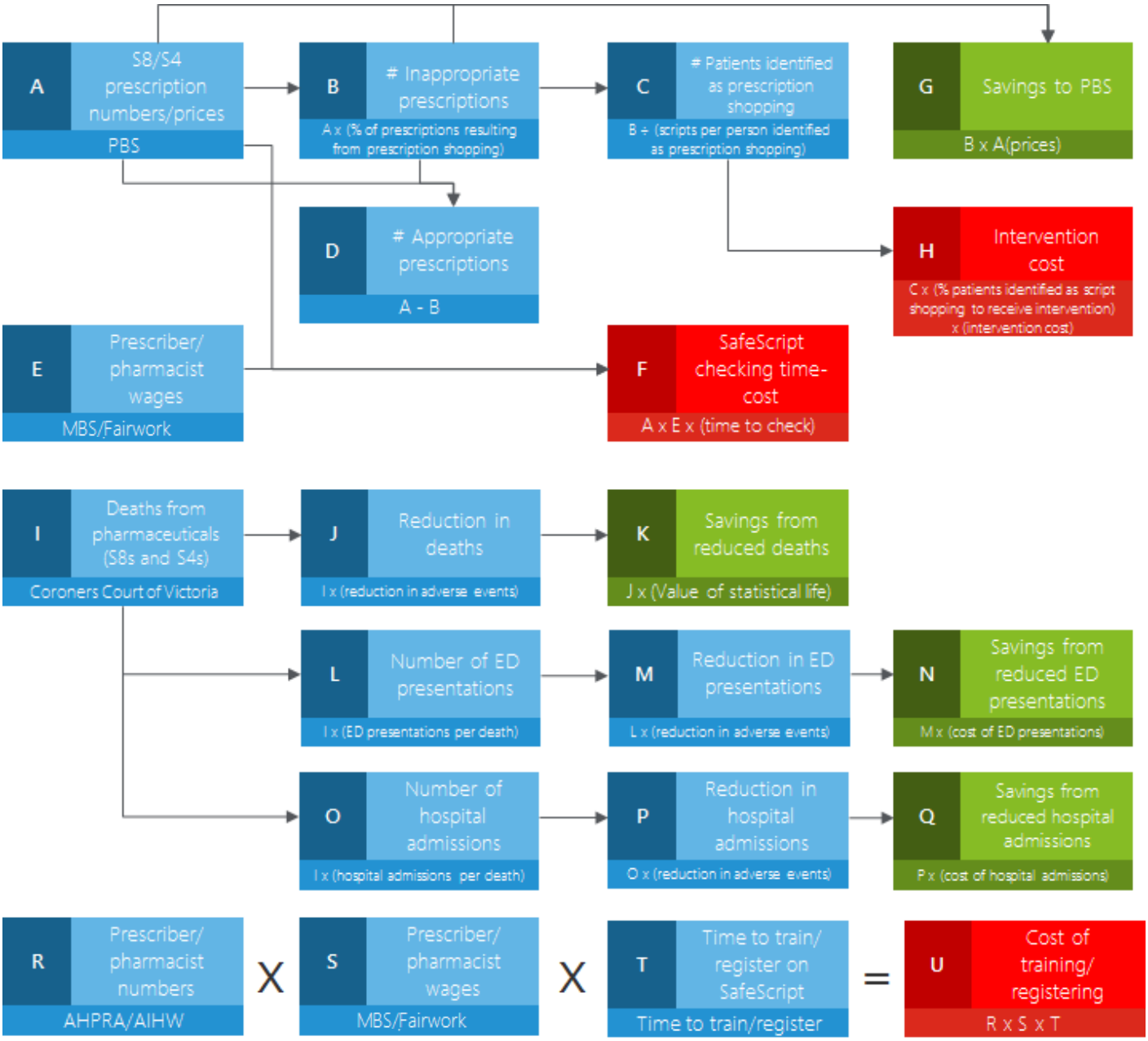
Figure 4.3 provides a simplified schematic of the model logic. The model combines parameters and assumptions, applies the model logic, and produces a series of costs and benefits which are weighed up to determine the net benefit of each option for SafeScript. While the actual model used contains more detail, the salient features of the model are captured in this schematic.

The calculations for boxes A-H calculate the costs and benefits that are largely related to prescription volumes. These are done separately for S8 poisons and selected S4 poisons to calculate the savings to the PBS, intervention cost, and prescription checking cost for each category of medicines. These results are combined for the case where S8 and selected S4 poisons are monitored.

Similarly, the calculations for boxes I-Q calculate the costs and benefits that are related to the incidence of harm contributed by each class of medicines. Again, these are computed separately for S8 and selected S4 poisons, and combined for the case where both S8 and selected S4 poisons are monitored.

The final row, boxes R-U, details regulatory burdens that are unlikely to vary with the coverage of medicines. These are the registration and training time costs involved that are borne by prescribers and pharmacists.

Figure 4.3: High level cost-benefit analysis model schematic



4.2.4 Modelling results

There are two main measures used for assessing a project's costs and benefits:

- The **benefit-to-cost ratio (BCR)**, which is calculated by dividing the present value of benefits by the present value of costs. This metric indicates the net return to society, factoring in all monetary and non-monetary costs and benefits.
- The **net present value (NPV)** is another useful measure of the benefit of a policy. While the benefit-to-cost ratio gives an indication of cost-effectiveness, the net present value gives an idea of the overall net benefit to society. It is calculated by subtracting the present value (PV) of costs from the PV of benefits.

Table 4.3 details the results from the cost-benefit analysis over the ten-year period 2018/19-2027/28.

Table 4.3: Cost-benefit analysis results for the ten-year period 2018/19-2027/28.

Note that totals may not be exactly equal to cost components due to rounding.

	S8s only	S8s and selected S4s
Costs (present values)		
Fixed costs	$47.2 million	$47.2 million
Registration and training costs	$3.9 million	$3.9 million
SafeScript checking costs	$71.0 million	$121.8 million
Cost of intervention	$9.3 million	$16.2 million
Total costs	**$131.5 million**	**$189.1 million**
Benefits (present values)		
Reduced deaths	$703.2 million	$2,155.6 million
Reduced ED presentation	$3.8 million	$11.8 million
Reduced hospital admissions	$10.4 million	$31.8 million
Total benefits	**$717.4 million**	**$2,199.2 million**
Net benefit		
Net benefit	$585.9 million	$2,010.1 million
Benefit-to-cost ratio	5.46	11.63

The results suggest that over ten years, SafeScript would achieve a net benefit of $586 million with monitoring of S8 poisons only, and a net benefit of $2 billion

when selected S4 poisons are monitored as well. Furthermore, monitoring both S8 poisons and selected S4 poisons is considerably more cost effective, with a higher BCR of 11.63 (rather than 5.46 for S8 monitoring only). While costs are 44% higher when monitoring S8 poisons and selected S4 poisons, the benefits are over three times higher when selected S4 poisons are included.

The significantly higher benefit to monitoring S8 poisons and selected S4 poisons is mostly due to the fact that the selected S4 poisons contribute to more deaths in total than S8 poisons do, and hence SafeScript would prevent more deaths by monitoring selected S4 poisons.

Based on available evidence from Austin Health (2017), DHHS considers that it is unlikely that the BCR and/or NPV would increase by monitoring additional S4 poisons (other than those selected), as the marginal benefits of monitoring those medicines using RTPM is expected to be lower than the marginal cost imposed on prescribers and pharmacists to check SafeScript each time they are prescribed or dispensed.

As such, the preferred coverage of medicines under SafeScript is both S8 poisons and the selected S4 poisons.

4.2.4.2 Other benefits

Although not the key aims of SafeScript, the system is expected to result in savings to the PBS. This is due to a lower amount of prescriptions being issued to patients who are obtaining supplies beyond therapeutic need. While these changes won't necessarily have direct effects on Victorians (and are therefore not considered in the cost-benefit analysis), they do offer sizeable savings to the Commonwealth, as shown in Table 4.4. These estimates were constructed by examining projections of S8 and S4 prescription volumes and prices, where these projections were already adjusted based on recent re-scheduling of medicines. It is important to note, however, that these benefits are highly variant to changes in Government policy or the re-scheduling of certain medicines on the PBS by the Pharmaceutical Benefits Advisory Committee (PBAC).

Table 4.4.: Present value of savings to the PBS, 2018/19 to 2027/28

	S8s only	S8s and selected S4s
PBS Savings	$35.9 million	$46.1 million

SafeScript may also result in fewer medical consultations as a result of the deterrence effect of the system on seeking out duplicative prescriptions for high-risk medicines, which would also result in savings to the MBS. However, the overall impact is unclear, as the introduction of the system may also result in an increase in the number of treatments given to patients that are identified as obtaining supplies of medicines from multiple prescribers, which could result in an increase in the payment of medical benefits under the MBS.

4.2.5 Sensitivity analysis

Any cost-benefit analysis inherently involves some uncertainty about the assumptions underlying it. In many cases, data is inexact or unavailable, and so

estimates and assumptions must be made to make up for these deficiencies. Due to this uncertainty, it is important to consider what the final results could be under different assumptions, a process known as sensitivity analysis.

A set of variations has been considered and compared to the default analysis of the preferred option (monitoring of S8 poisons and selected S4 poisons) outlined in Table 4.5. These variations are all expected to increase the costs or decrease the benefits of SafeScript, and so are forms of stress testing to determine whether a more pessimistic view regarding the effectiveness and efficiency of SafeScript still leads to a net social benefit. The variations considered are:

- Decreasing the effectiveness of SafeScript from 12% to 5% (to become as effective as the non-mandatory Tasmanian system).
- Increasing the time to check SafeScript from 1 minute to 3 minutes.
- Increasing implementation cost from $29.5 million to $60 million.
- Increasing the average amount of training time for prescribers and pharmacists from 30 minutes to 120 minutes.
- All of the above.

The results from these variations are shown in Table 4.5 below.

Table 4.5: Results from the sensitivity analysis compared to the preferred option (monitoring of S8 poisons and selected S4 poisons) from the default analysis (expressed in present value terms)

Case	Costs	Benefits	Net benefit	Benefit-cost-ratio
Default analysis	$189.1 million	$2,199.2 million	$2,010.1 million	11.63
Effectiveness of SafeScript reduced from 12% to 5%	$189.1 million	$974.3 million	$785.1 million (329 fewer lives saved)	5.15
Increasing time to check script from 1 minute to 3 minutes	$432.7 million	$2,199.2 million	$1,766.4 million	5.08
Increasing implementation cost from $29.5 million to $60 million	$219.0 million	$2,199.2 million	$1980.1 million	10.04
Increasing average prescriber and pharmacist training time from 30 to 120 minutes	$197.0 million	$2,199.2 million	$2,002.2 million	11.16
All of the above variations	$470.5 million	$974.3 million	$497.3 million	2.07

The results suggest that even with large reductions in the assumed effectiveness and efficiency of SafeScript, the system would still yield a net social benefit. The change with the most financial impact stems from more than halving the ability of SafeScript to save lives, but even with this change SafeScript yields a positive benefit and benefit-cost-ratio.

These scenarios are considered unlikely to be realised because:

- Due to the mandatory nature of SafeScript (following the initial transition period), it is expected to be significantly more effective than the Tasmanian system, although it is possible that it could still have less than 12% effectiveness.
- The 3 minute checking time is highly unrealistic. As detailed in Section 4.2.1.3, 1 minute is already considered an upper bound, with most SafeScript checks expected to be measured in seconds rather than minutes.

Given the results of the sensitivity analysis, DHHS considers it is reasonable to conclude that SafeScript is highly likely to return a net benefit to society, given the comparatively low level of investment required for a high number of averted deaths.

4.3 Design Choice 2 – Exceptions from mandatory use: qualitative analysis

The proposed Regulations specify several settings and circumstances under which prescribers and pharmacists are exempt from mandatory checking of SafeScript. These exceptions are being proposed in order to balance patient safety with prescriber and pharmacist regulatory burden, associated with mandatory use.

These exceptions were determined following consideration by the EAG of the exceptions in place with regards to existing regulatory controls for S8 poisons in Victoria (such as the S8 permit system), and the exceptions in mandatory monitoring systems from case studies based in the US. The EAG's recommendations are generally aligned with these existing regulatory exceptions.

The exceptions are proposed because there are a number of settings and circumstances where patients receive medicines under close supervision and the risk that a patient would be supplied medicines from multiple providers is low. If the prescriber or pharmacist does suspect drug seeking behaviour or dependence in a patient who falls into an exception category, it would still be possible for prescribers and pharmacists to check SafeScript at their discretion. However, imposing a blanket regulatory burden in these environments would introduce unnecessary costs that would be unlikely to provide any benefit.

The rationale for each exception clause is discussed below and focuses on how the exception performs against two criteria:

1. Risk of harm – the likelihood of inappropriate use in these settings and circumstances, and the extent of potential harm.
2. Efficiency – the extent of the regulatory burden that SafeScript would impose on health professionals in these settings and circumstances, relative to the harm that it would prevent.

4.3.1 Options 1-4: Highly monitored settings

The proposed Regulations state that a registered medical practitioner, nurse practitioner or pharmacist who is required to check the monitored poisons database before prescribing or supplying a monitored medicine to a patient is exempt from this requirement where the patient is:

(a) an in-patient being treated in a hospital; or
(b) a patient being treated in an emergency department of a hospital; or
(c) a patient being treated in a prison or police gaol; or

(d) a resident being treated in an aged care service.

The exception from checking the monitored poisons database in relation to a hospital in-patient or emergency department patient does not apply where the patient is prescribed or supplied a monitored supply poison on discharge.

Note: SafeScript will not collect records of in-patient administration in hospitals or prisons, as in these settings medicines are administered via medication charts (not prescriptions), and medicines provided by clinical staff are consumed by the patient within the hospital or prison setting.

Risk of Harm

The risk of harmful use of prescription medicines in these settings is low, as medicines are supplied or administered to patients under close supervision and within a closed environment, and as such, patients are unlikely to be able to obtain medicines from multiple providers. It was noted by Austin Health (2017), that there is some evidence of deliberate misuse of prescription medications in prison settings in the US and UK, caused by patients falsifying symptoms. Given SafeScript does not collect records of in-patient administration or supply of medicines, the only source of prescribed medicines in prisons is from a prison prescriber, and prison clinicians will have records at hand of what medicines have been supplied while in prison, imposing a mandatory requirement to check SafeScript before prescribing in these settings is unwarranted. Even if patients in these settings were able to access an inappropriate supply of medicines, in the event that an adverse event or overdose occurred, it is likely that medical help would be close at hand.

Exempting health practitioners from the requirement to check SafeScript before prescribing or supplying monitored supply poisons in these settings is also consistent with exceptions from S8 permit requirements legislated in the Act. Section 34F exempts prescribers treating patients in prisons, police gaols, aged care services and hospitals from the usual S8 permit requirements. One of the reasons stated for this exception is "in confined circumstances where 'doctor shopping' is not possible, the risk of dependency is greatly reduced" (*Drugs, Poisons and Controlled Substances Amendment Bill 2008*, Explanatory Memorandum, 2008). Since these exceptions were introduced, there have been no concerns raised or evidence presented to DHHS which suggest that these settings are no longer considered appropriate.

In the case of hospital settings, including in-patients and emergency department patients, it is proposed that the exception only applies when the patient is being treated within the hospital. In the instance that a patient is supplied with or prescribed a monitored medicine on discharge, it will be mandatory for the health practitioner to check SafeScript because this situation is akin to a 'standard' prescription scenario, where the patient will receive a supply of medicines to take home without supervision.

Cost

The excepted settings included in the Regulations are largely consistent with exceptions in place for the prescribing of S8 poisons in Victoria. Section 34F of the *Drugs, Poisons and Controlled Substances Act 1981* exempts prescribers treating patients in prisons, police gaols, aged care services and hospitals from the usual S8 permit requirements. The second reason that this exception was included was that "it reduces the administrative burden for practitioners in these circumstances"

(*Drugs, Poisons and Controlled Substances Amendment Bill 2008*, Explanatory Memorandum, 2008). Daniel Andrews, the Minister for Health at the time further confirmed the importance of this point by stating in the Second Reading Speech that "there are certain settings where the permit provisions impose an unnecessary administrative burden and, in some cases, work against good treatment practices" (Second Reading Speech, 2008).

Outcome

Providing for exceptions in these settings reduces the regulatory burden on healthcare professionals without compromising patient safety. Importantly, practitioners will still have access to SafeScript in these settings and it can be used when deemed clinically appropriate for patients (e.g. when a patient is admitted to hospital with a suspected adverse event or overdose of a drug), rather than as a mandatory requirement each time a patient is prescribed or supplied a monitored medicine. Reflecting this, Options 1-4 are preferred options.

4.3.2 Option 5: Palliative care patients

The proposed Regulations state that a registered medical practitioner, nurse practitioner or pharmacist who is required to check the monitored poisons database before prescribing or supplying a monitored medicine to a patient is exempt from this requirement where the patient is:

(a) the person is suffering an incurable, progressive, far-advanced disease or medical condition; and
(b) the prognosis is of limited life expectancy due to the disease or medical condition; and
(c) the supply of the monitored supply poison is intended to provide palliative treatment; and
(d) the person is not a drug-dependent person.[7]

Risk of Harm

For patients who are diagnosed with a terminal illness or disease, where the condition is advanced and has a poor prognosis, the focus of care is on providing symptom relief and increasing quality of life.

The intent of treatment in these circumstances is for palliation rather than for curative purposes. When treatment is closely supervised under the regular care of health professionals, obtaining supplies of medicines from multiple prescribers without co-ordinated treatment is considered unlikely in this cohort of patients, though the quantity of medicines may increase as the illness progresses.

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[7] In the context of the treatment of a palliative care patient, a health professional may have reason to believe a patient is a drug-dependent person if aberrant drug-related behaviours are present, for example, where the patient:

- has had multiple unsanctioned dose escalations of prescribed medicines
- has admitted current misuse or abuse of pharmaceutical medicines or illicit drugs
- has obtained medicines beyond therapeutic need from multiple prescribers
- is forging prescriptions or obtaining medicines by false representation
- has been selling or sharing prescription medicines
- shows physical signs of intravenous drug use.

Risk does exist when exempting clinicians from the need from checking SafeScript when prescribing or supplying monitored medicines to palliative care patients, as some could exploit the exemption in order to stockpile medicines for financial gain, or for the use of friends and/or relatives. This risk may need to be considered during the evaluation of SafeScript in order to ensure that the exemption relating to palliative care patients does not provide a pathway for black market medicine supplies, or the exploitation of palliative care patients.

Cost

The prescribing of medicines for palliative care purposes may become more frequent as the disease progresses and additional symptom relief is necessary, for example, the increased prescribing of opioids when stronger and more frequent pain relief is required. In these circumstances, where the medical diagnosis and the clinical need for a medicine are clear, the utility of checking SafeScript is low. Hence, it would not be an appropriate regulatory burden to require health professionals to check SafeScript on every occasion a monitored medicine is prescribed or supplied, particularly when it can be expected that frequency of prescribing and supply of medicines by a patient's prescriber and pharmacist may increase as a terminal illness progresses.

Again, however, practitioners will have access to the database and may choose to check SafeScript if they have any concerns about the issuing or dispensing of prescriptions.

Outcome

Reflecting the relatively low risk of harm, and the increased cost associated with checking SafeScript in circumstances when relatively frequent prescribing may occur, an exception from the mandatory requirement to check SafeScript where patients are being provided with palliative treatment is also DHHS's preferred option.

4.3.3 Option 6: Cancer patients

Exceptions from the mandatory requirement to check SafeScript were considered for cancer patients, as there are existing S8 permit exceptions relating to the treatment of patients with cancer pain.

Risk of harm

Since the S8 permit system was introduced and S8 permit exceptions were provided for prescribers treating patients with cancer, advances in medicine have meant that overall, the survival rates for patients with cancer are generally increasing. Whereas, a diagnosis of cancer was previously considered likely to be terminal, this is no longer the case in some circumstances. Patients living with cancer may now survive for many years after a diagnosis is made. As such, there is a greater chance that drug dependency could occur, given the longer periods that patients could be prescribed high-risk medicines, such as high-dose opioids for pain relief.

Cost

There would be cost savings associated with providing an exception to checking SafeScript when prescribing or supplying a monitored medicine to cancer patients.

Outcome

As overall cancer survival rates are increasing, patients with cancer may be prescribed higher doses of opioids for longer periods of time than previously.

Given the risks of prescription medicine misuse or overdose increases when patients are prescribed higher doses of opioids for an extended period, providing an exception from the mandatory requirement to check SafeScript when treating any patient with a cancer diagnosis is not DHHS's preferred option.

However, for patients diagnosed with terminal cancer that has limited prognosis, the exception relating to palliative care patients (Option 5) will be still applicable for practitioners treating patients in this category.

4.3.4 Option 7: Supplies of 7 days' medication or less

The option to exempt prescribers and pharmacists from checking SafeScript when providing a short supply of medicines was also considered by DHHS.

Risk of harm

Exempting prescribers and pharmacists from checking SafeScript when prescribing or supplying short duration prescriptions is considered unlikely to prevent patients from obtaining supplies of medicines beyond therapeutic need, as patients may request short duration prescriptions from multiple prescribers and avoid detection. While the risk of harm may be lower for shorter duration prescriptions (relative to longer duration prescriptions), it is still possible for such instances of supply to cause serious harm, particularly where patients visit multiple prescribers to obtain various high-risk medicines and those prescribers are not aware of one another's actions.

Cost

Providing exemptions for short duration prescriptions is likely to increase the overall cost of SafeScript, as patients who are obtaining supplies beyond therapeutic need would not necessarily be deterred, but would (on average) require more visits to doctors and pharmacists in order to obtain the same amount of prescription medicines as they were prior to SafeScript. This would require more time on the part of prescribers and pharmacists, of which that time could be more efficiently spent attending to other patient concerns and needs.

Outcome

Based on the high risk of harm, and potential for increased costs, Option 7 is not DHHS's preferred option.

4.4 Design Choice 3 – Choice of data source entities

Two main options exist for data source entities that will be able to populate SafeScript with information on prescriptions. The first option is the use of Prescription Exchange Services (PESs), which are electronic systems that are connected to medical prescribing and pharmacy dispensing systems to collect prescription records, whereas the second option involves requiring every prescriber and pharmacist to individually provide records to SafeScript through records entered in medical prescribing and pharmacy dispensing software.

4.4.1 Option 1: Prescription Exchange Services (PES)

PESs are electronic prescription repositories which were developed to support national e-health initiatives, including the electronic transfer of prescriptions. PESs are databases that interact with prescribing and dispensing software used by prescribers and pharmacists to facilitate the communication and verification of electronically created prescriptions.

These databases already collect much of the information needed for SafeScript, and so the system has been designed to interface directly with PESs to take advantage of the capabilities that already exist.

Under this option, pharmacists who have created a record of supply of a monitored poison using an electronic system that is compatible with a PES must register with the PES and provide the record of supply to the PES at the time the record of supply is created. With a compatible electronic system, there is no net cost associated with registering with a PES.

DHHS expected this to have minimal impact on pharmacists, since over 90% of pharmacies are connected to a PES, meaning that the majority of pharmacists are already transmitting records as part of national e-health programs through a PES. No costs are incurred by pharmacists to send data to a PES. Further, pharmacists who have compatible software, but are not switched on yet to a PES, can register at no net cost. Following a request from a pharmacy to activate the PES, DHHS considers the time required to complete the installation process is minimal, and may be performed remotely via the PES provider with minimal disruption to practice workflow.

Pharmacies that are currently not using PES-compatible software (that is, most hospital pharmacy departments that use one of two hospital dispensing systems) will not be compelled to use software that is PES-compatible. DHHS will work with these two software vendors to develop integration services to collect records from these pharmacies at a subsequent stage of implementation and it is aimed that this will be completed by mid 2020.

When these additional records become available in SafeScript, the Regulations may require an amendment to include the sources of these records as *data source entities* should they not originate from a PES-compatible system. Consultation with relevant stakeholders will take place before Regulation amendments to include new data source entities are made.

Records from pharmacies not using PES-compatible software will not be included in SafeScript when it is initially introduced, which may impact on the initial effectiveness of the system during the implementation phase. However, these pharmacies will still have access to log in to SafeScript to view records.

4.4.2 Option 2: Prescriber and pharmacist prescription software

A second option considered would be to obtain data from pharmacists via direct integration with every dispensing software used in pharmacies, which is the approach taken in the Tasmanian RTPM implementation.

The costs with this option that are not present under Option 1 include the associated costs of developing and installing new integration services with all pharmacies to source data rather than leveraging from existing integration services already established and in use. In comparison with Tasmania, where there are approximately 150 pharmacies, there will be a substantial cost to implement this approach in Victoria, where there are over 1,300 pharmacies in operation.

4.4.3 Preferred Option

While the second option is already operational in the Tasmanian context, DHHS deemed this unsuitable in Victoria due to the scale of implementation in Victoria and the efficiency of obtaining data from only two PESs as opposed to integrating

with at least 12 separate pharmacy systems. Further, leveraging the PES infrastructure will provide for a system that will be scalable at a national level and a user experience that is incorporated into existing clinical workflows.

As a result, the PESs (Option 1) are DHHS's preferred choice of data source entities.

4.5 Design Choice 4 – Information required from prescribers and pharmacists

Further, leveraging the PES infrastructure will provide for a system that will be scalable at a national level and a user experience that is incorporated into existing clinical workflows. As such, patient date of birth is the preferred option, as a key identifier that enables the successful matching of patient records in SafeScript.

Under this approach, a prescriber who issues a prescription for a monitored poison must include the patient's date of birth on the prescription, and a pharmacist who supplies a monitored poison must include the date of birth in the record of supply, in addition to the information already required to be provided when a prescription is issued or dispensed.

The cost of collecting and recording this information for each patient has not been explicitly quantified in the cost-benefit analysis in section 4.2, due mainly to the lack of supporting data on the number of patients accessing monitored poisons (rather than the number of prescriptions).

The following sections examines qualitatively how this requirement would impact on prescribers and pharmacists.

4.5.1 Burden on prescribers

The proposed Regulations require that any person who writes a prescription for a monitored poison must include the patient's date of birth on the prescription. While this imposes an extra regulatory burden on prescribers, this is likely to be small for the following reasons:

- For prescribers, patients' date of birth records are collected when creating a patient's medical file, which is saved for subsequent visits.
- Medical prescribing systems save a patient's date of birth in their file, meaning that this does not have to be entered each time a prescription is issued electronically – it only has to be recorded on the first visit.

Under existing Regulations, the date of birth is a requirement only on prescriptions issued for S8 poisons. This requirement was introduced in Regulations in May 2017 and required small changes to practice software to be made to print the date of birth on prescriptions for S8 poisons. The proposed Regulations will now extend this requirement to include all monitored poisons (i.e. additional selected S4 poisons). DHHS is working with the Medical Software Industry Association (MSIA) to ensure this new requirement will be communicated to all software vendors in order to support health professionals more efficiently meet this new requirement. MSIA has advised that vendors will be able to accommodate for changes to regulatory requirements with adequate notice.

The automated inclusion of date of birth on electronically issued prescriptions for monitored poisons will minimise the regulatory impact of this requirement for prescribers. In a survey conducted on a Victorian Primary Health Network, it is estimated that ~97% of GP clinics use an electronic prescribing system (Victorian

Primary Health Network Alliance, 2017). The regulatory burden on workflow for the remaining prescribers who do not yet use electronic systems and handwrite prescriptions is expected to be greater than those who are using an electronic prescribing system.

As with existing Regulations, the proposed Regulations will not require prescribers to use an electronic prescribing system. While the proposed Regulations may result in some clinicians opting to upgrade to an electronic prescribing system to more efficiently comply with regulatory requirements, there are a range of other efficiencies and benefits associated with doing so than compared to maintaining paper-based records. Electronic prescribing systems provide for a more efficient method of creating, storing and retrieving a patient's medical file, which includes the history of all prescriptions issued at the clinic, diagnostic, pathology, and imaging results, hospital and specialist reports, issuing of medical referrals and certificates, and clinical progress notes. The cost to clinicians who elect to upgrade to an electronic system should therefore not be solely attributable to the introduction of SafeScript.

Given that the proportion of prescribers who are not using an electronic prescribing system is small (~3%) and the additional regulatory burden for prescribers is only applicable to prescriptions for selected S4 poisons (as the existing requirement for date of birth already includes prescriptions for all S8 poisons), DHHS does not expect the aggregate effect of including date of birth on prescriptions for selected S4 poisons to be large.

4.5.2 Burden on pharmacists

The proposed Regulations require that a pharmacist who supplies a monitored poison must include the date of birth in the record of supply.

The regulatory burden imposed on pharmacists is expected to be low. This is because, like prescribing software, patient date of birth is a standard data field on a patient's file within dispensing software and is saved between pharmacy visits, meaning that it only need to be entered once for each patient. Given the once-off nature of the collection of date of birth information, DHHS considers that the additional time required of pharmacists is likely to be low.

4.5.3 Summary

Given once-off nature of the collection of date of birth information, DHHS expects the costs of collection to be small, as it is only expected to minimally extend the time required to comply with regulatory requirements when writing or dispensing a prescription. For initial patient visits, the extra time would be taken to collect and enter date of birth information (in cases where this data is not already on file). For subsequent patient visits, there would no additional time taken for prescribers or pharmacists to collect and enter date of birth information, except in the case of handwritten prescriptions, which would require prescribers to write this additional information by hand – noting that this requirement already exists when prescribing S8 poisons.

This burden will not materially affect the BCR of RTPM. The sensitivity analysis demonstrates that, if the costs of recording patient date of birth is included in the checking costs and these costs are increased by two minutes for every prescribing and dispensing event (not just the first event for each patient), RTPM would still retain a positive NPV and BCR.

4.6 Summary: preferred design choices

4.6.1 Preferred Design Choice 1

The cost-benefit modelling in Section 4.2 indicates that an RTPM implementation where selected S4 poisons that are causing significant harm are monitored in addition to S8 poisons would result in a significantly greater net benefit than a system that monitors S8 poisons alone. This is predominantly due to the large benefits derived from saving additional lives, since there are more deaths involving the selected S4 poisons than S8 poisons. While these S4 poisons are not as dangerous by themselves, they are more readily accessible due to their lower regulatory controls compared with S8 poisons and hence involved in a greater number of deaths, particularly when combined with other medicines or substances.

4.6.2 Preferred Design Choice 2

The qualitative analysis in Section 4.3 shows that exempting certain settings and circumstances will reduce the regulatory burden otherwise introduced by SafeScript. This is because these settings are closed environments in which the risk of patients obtaining supplies of medicines beyond therapeutic need—and potential for harms—is limited.

4.6.3 Preferred Design Choice 3

The analysis in Section 4.4 demonstrates that implementing a system that interfaces with PESs would be more efficient than one which interfaces directly with the software systems used by prescribers and pharmacists. Further, leveraging the PES infrastructure will provide for a system that will be scalable at a national level and a user experience that is incorporated into existing clinical workflows. As such, PESs are the preferred option for data source entities in the Regulations.

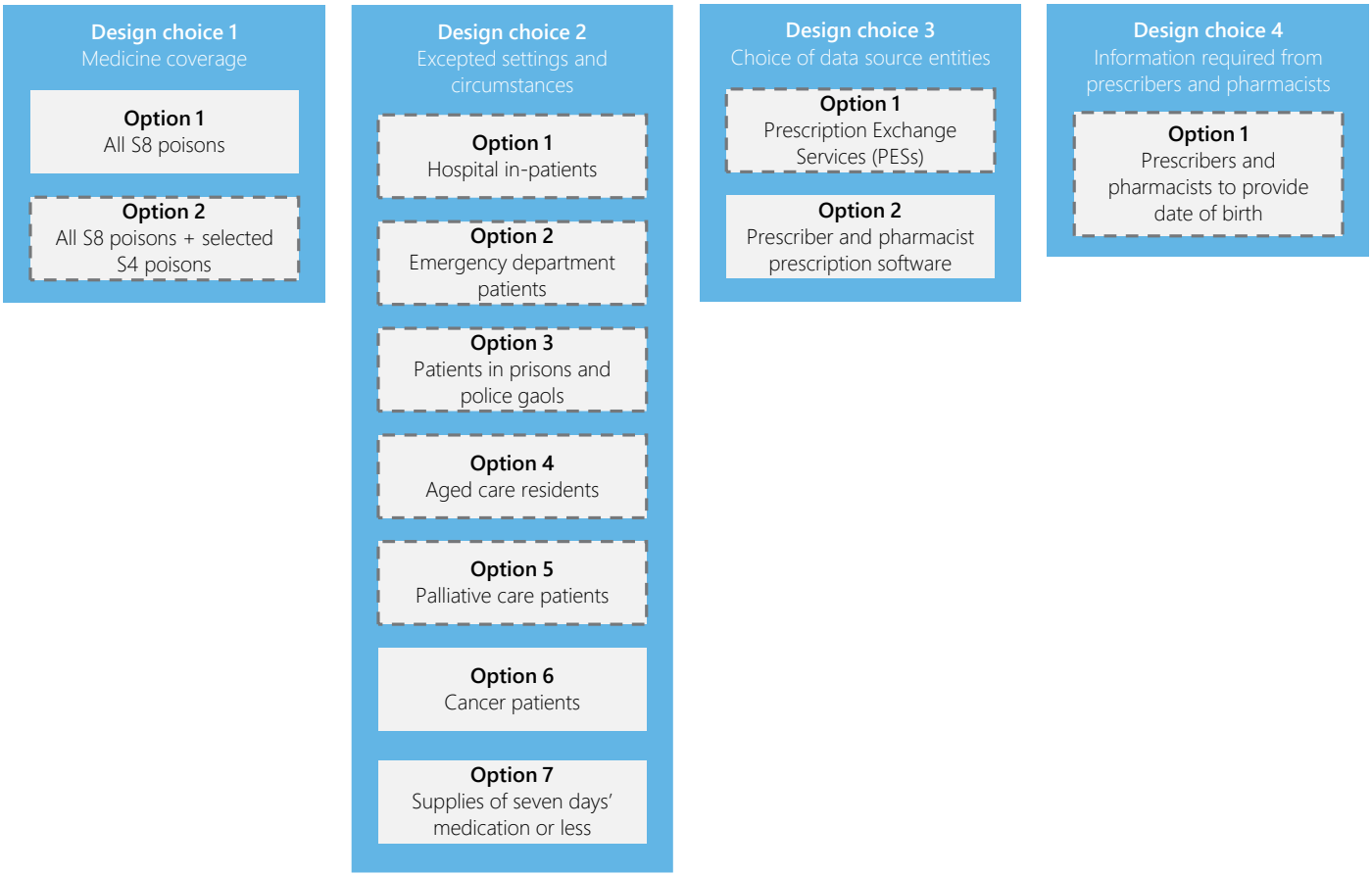
Under this option, pharmacists who have created a record of supply of a monitored poison using an electronic system that is compatible with a PES must register with the PES and provide the record of supply to the PES at the time the record of supply is created.

4.6.4 Preferred Design Choice 4

In order to be an effective source of information for health professionals, a reliable and robust method of matching patient prescription records is necessary. The option of requiring the collection of a patient's date of birth is considered appropriate to improve data matching, however this may impose a small burden on some prescribers and pharmacists. The analysis in Section 4.5 suggests that the burden of this requirement would have is likely to be low.

These design choices are summarised below in Figure 4.4.

Figure 4.4: An overview of the design choices and preferred options (dashed outline on preferred options).



4.7 Impact on small business

The Victorian Guide to Regulation (OCBR, 2016) states that a RIS should, where relevant, summarise the impact that proposed regulations would have on small business.

As nearly all GP clinics (97%) and a majority of pharmacies (59%) in Victoria are considered small businesses, much of the impact of the proposed Regulations (and on SafeScript more broadly) will indeed be borne by small businesses (defined by the ATO as those with an annual turnover of less than $2 million) (ABS, 2016).

However, SafeScript is not likely to impact these businesses in a material way, either financially or in a broader operational sense, because:

- Early consultations undertaken during the planning for implementation of SafeScript, general practitioners and pharmacists indicated that a majority of clinics and pharmacies have existing IT capabilities (a computer, the internet) to access SafeScript. SafeScript will link with clinician desktops and integrate with existing clinical workflows, to provide information within a short period of time.
- For those that do not have such infrastructure, there will be provisions for accessing SafeScript information through telephone enquiries with DHHS. For these businesses, the time associated with checking patients' prescription records may be greater than for businesses with online access to SafeScript, as

additional authentication methods will be required to verify the identity of the caller making an enquiry to DHHS about a patient's SafeScript history.
- The Victorian Government will fund implementation and training costs, and so accessing SafeScript is not expected to impose a financial burden on businesses.
- Compliance activities will be largely able to be conducted by DHHS through data analytics approaches on SafeScript, minimising the burden on prescribers and pharmacists from periodic reporting.
- It is expected that any impact on businesses by the loss of staff due to training or registration requirements will be minimal, as training and registration will be available online and can be accessed at any time. Where any gaps in training needs are noticed, support will be provided by DHHS as they are identified.

While there will be a requirement for a small number of pharmacies to activate their pharmacy software's connection to a PES, DHHS considers this approach is reasonable, given the significant public health benefits from the implementation of SafeScript and that the leveraging of existing PES infrastructure will impose the least additional impact to existing pharmacy workflows.

4.8 Impact on competition

The Victorian Guide to Regulation (OCBR, 2016) states that a RIS should summarise the competition effects of proposed new regulations. This is to ensure that any new regulations comply with the Competition Principles Agreement (to which Victoria is a party), which requires that primary and subordinate legislation should not adversely restrict competition unless such restriction gives rise to benefits which outweigh the costs.

It is likely that the introduction of SafeScript will have limited, if any, effect on competition, either between existing market participants, or between existing market participants and new entrants, for the following reasons:

- The Victorian Government is funding implementation and training costs, meaning that these costs will not be disproportionately high for smaller businesses/practices (which they otherwise may have been).
- SafeScript will interface with existing software which is already used by the majority of small businesses.
- Where prescribing/dispensing software is used, the burden of checking SafeScript will be low, and uniform for every prescribing and dispensing event.
- SafeScript is ubiquitous across the Victorian industry – it affects all prescribers and pharmacists in the same way. No particular segment of the market will have a competitive advantage as a result of SafeScript.

While the SafeScript infrastructure is based on obtaining prescription records collected from the two current PES providers, the system has been designed to not preclude from integrating with other services and is capable of including records from future PES providers or any other data source where records of supply of prescription medicines are collected.

4.9 Possible unintended effects or risks of the proposed Regulations

While the introduction of the proposed Regulations are expected to reduce the level of harm caused by high-risk prescription medications in Victoria, unintended consequences could still arise:

1. As Victoria is likely to be the first mainland state to implement RTPM, there is a risk that its effectiveness will be reduced by the ability of patients who are obtaining supplies beyond therapeutic need to travel interstate to obtain medicines. While the proposed Regulations will not apply to non-Victorian practitioners (meaning that they won't have access to the database), the proposed Regulations will enable Victoria to collect all prescribing and dispensing records available in the PESs that have a Victorian nexus, (i.e. where the record contains either a Victoria prescriber, Victorian pharmacy or a Victorian patient). This would allow Victorian health practitioners to view records of prescriptions written or dispensed interstate for Victorian patients. While ultimately a national system is the goal (and the Act facilitates the sharing of data between Victoria, Commonwealth and other states and territories), this intermediate step will partially address cross-border issues while other jurisdictions progress with implementation of RTPM.

2. The introduction of the proposed Regulations may result in an increase in demand for some support services, such as alcohol and drug treatment services. Some funding has been allocated for minor enhancements to counselling and treatment services for patients who are identified as misusing prescription medicines. DHHS will monitor the demand for these and other services during the implementation stage of SafeScript (See Section 6.3). While this may result ultimately in additional costs to the Victorian Government, there would be additional benefits that arise from these interventions that are not included in the cost-benefit analysis. These may include improved social outcomes or enhanced work productivity for individuals who are identified and treated for their addiction.

3. It is possible that the introduction of SafeScript may introduce a deterrent for clinicians in the prescribing or dispensing of monitored medicines, known as a "chilling effect". Some prescribers and pharmacists may perceive that as their prescribing and dispensing actions will now be visible to other practitioners as well as to regulators (DHHS), that they may decide to no longer supply these medicines to patients to avoid scrutiny by their peers or regulators against the possibility of concerns being raised about inappropriate prescribing or dispensing practices. The workforce training that will be delivered as part of the implementation of SafeScript will provide education to prescribers and pharmacists on appropriate practices when using SafeScript to try to minimise chilling effects.

5 Implementation plan

5.1 Implementation and transitional arrangements

The introduction of SafeScript will represent a major change in the way that S8 and certain S4 poisons are prescribed and dispensed and will result in changes to clinical practice.

This chapter summarises the manner in which the Regulations will be implemented, including phase-in arrangements. An overview of the timing of various elements of SafeScript implementation is shown below:

Implementation Plan	2017		2018				2019				2020	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Preparation of proposed Regulations and consultation												
Regulations made and in operation												
Procurement of IT system												
Build and test IT system												
Implementation of SafeScript to health professionals												
Mandatory use of SafeScript commences												
Develop workforce training												
Implement workforce training												
Develop public awareness campaign												
Implement public awareness campaign												

The $29.5 million funding allocated by the Victorian Government to implement SafeScript includes both costs that have already been incurred, and costs that are yet to be incurred (i.e. it includes the cost of all activities outlined in the implementation plan above).

5.2 Implementation

SafeScript will be initially implemented in a single area and evaluated before being rolled out across the state. During the first 18 months of operation it will not be mandatory for medical practitioners, nurse practitioners and pharmacists to check SafeScript in order to allow clinicians to become familiarised with the use of SafeScript and incorporate it into their clinical practice.

While this phased approach will mean that there may be regions that will not have access to SafeScript at the commencement of implementation, SafeScript will still

be collecting data state-wide from the beginning, with the phased approach allowing local issues to be identified and readily addressed in the initial phases.

It is expected that phased implementation will be completed across Victoria in 2019, providing a sufficient period of time for clinicians in all regions to have access and become familiar with SafeScript before mandatory use of the system commences from 1 April 2020.

5.3 Responsibilities

5.3.1 Implementation

The Real-Time Prescription Monitoring Implementation team within DHHS will be responsible for overseeing all changes brought about by the implementation of SafeScript, including the changes to the Act and the proposed Regulations. This approach ensures that all aspects of the introduction of SafeScript, including stakeholder management and communication, are co-ordinated.

The EAG will continue to meet across the implementation period and will provide valuable advice to DHHS as SafeScript is put in place.

5.3.2 Administration

DHHS will also be responsible for administering and monitoring health professional compliance to ensure they meet their legal obligations in using SafeScript appropriately.

DHHS will have the regulatory understanding and technical skills to understand how and why SafeScript should be used. Additional system-specific training within DHHS may be required. The cost of this training is included in the $29.5 million of funding set aside.

5.4 Communications

DHHS will develop and implement a public awareness campaign as part of its roll-out of SafeScript. This will include a change management plan in relation to the legislation and regulations. The cost of this public awareness campaign is included in the Victorian Government's $29.5 million funding.

Key messages associated with the use of SafeScript will be integrated into training discussed in section 5.5 and other communications to be undertaken as part of the roll out of SafeScript.

The public awareness plan is currently being developed and will include the following:

- Roll out of a media and advertising campaign to raise public awareness of the current problem related to the harm from prescription medicines, and to create support for SafeScript as a positive and necessary change.
- Development of communication material for consumers and health professionals to provide details about the change, and prepare each audience group for the change and inform them about key impacts.
- Information sessions for the general public and consumers to prepare them for the change and improve prescription medicines literacy.

The effectiveness of the communication plan will be evaluated by measuring the changes in awareness, attitudes, beliefs and behaviour related to prescription

medicines before the commencement of the campaign and after the campaign is completed. Details are provided in the Evaluation Strategy (Section 6).

5.5 Training

Training is a key aspect of implementation that was identified during the planning work for real-time prescription monitoring. Training is currently being developed and will be delivered primarily to medical practitioners and pharmacists. A partnership with the Victorian Primary Health Networks and NPS MedicineWise has been established to deliver the training. Materials to be covered in the training will be created after undertaking an analysis of needs and gaps with stakeholders. The financial cost of this training is included in the Victorian Government's $29.5 million funding towards SafeScript.

Training will be split into three content streams, outlined in the table below. The first stream of training is highly relevant for all users to operate SafeScript, and will be delivered online. It is estimated that it would take 30 minutes to complete this stream, as this is the core information that prescribers and pharmacists would be required to know to be able to operate SafeScript (see Appendix A).

Streams 2 and 3 will be offered to all prescribers and pharmacists, however the content of this training goes beyond what is required to operate SafeScript, but is of equal value as it provides clinicians with the necessary skills in the safe and appropriate clinical management of patients who may have been identified through SafeScript. DHHS may target this training to certain clinician groups or geographical regions, based on need. Undertaking this training would extend beyond the 30 minutes allocated for Stream 1.

The sensitivity analysis (see section 4.2.5) highlights that, even if the uptake of this training is high, such that average training time for prescribers and clinicians is longer than 30 minutes, this will not significantly impact on the overall BCR.

Table 5.1: Training content streams

Stream	Content
1. SafeScript technical and other related advice.	• How do I register with and access SafeScript? • How do I use SafeScript in a way which integrates it within existing workflow (people, process and system)? • How do I use SafeScript and maintain patient privacy? • What are the regulatory obligations associated with SafeScript and the S8 permit system?
2. Education on better practice approaches to individual care and supports.	• What does safe and appropriate prescribing of S8 poisons and other high-risk medicines look like? • What does better practice counselling and support for prescription medicine dependence and tapering of prescription medicines look like? • How do I maintain my safety and those of my staff members when prescribing or dispensing is not appropriate? • What does better practice clinical decision-making look like within pharmacy? • What does better practice for pain management and other issues look like?

	• How can better practice opioid replacement therapy be delivered? • In light of the above, what does the complete better practice model of care look like? What are the desired roles and contributions of prescribers and pharmacies?
3. Provision of advice to refer to relevant specialist pathways.	• What should guide clinical determination of whether a patient needs referral to a specialist service? That is, what are the thresholds? • What are the localised referral pathways requiring prescription medicine addiction and support services for other conditions? • How can I continue to meet the needs of patients that are accessing these services, that are awaiting first appointment at specialist services, or that decline to engage in services? • Who can I contact for immediate clinical advice on patient related matters? Who can I contact for broader advice on whole-of-organisational changes that need to be made to deliver the complete better practice model of care?

Source: DHHS

A number of issues will be addressed under each content stream. The aim of the training is to ensure the proper use of SafeScript and also to improve clinical care and patient safety. Training will also take into consideration treatment options for patients other than prescription medication and will aim to upskill health practitioners in the areas of pain management and addiction medicine. Consequently, patients should be in a better position to receive the most appropriate intervention for them, in a timely manner. Details of time-cost associated with training are provided in Section 4.2.1.2.

5.6 Compliance

5.6.1 Encouraging compliance

As part of the roll out of SafeScript, DHHS will provide training and development packages to medical practitioners, nurse practitioners and pharmacists to educate them on the appropriate use of SafeScript, and to encourage its use as a clinical tool to promote better treatment decisions. As noted above, training will include advice on how to use SafeScript, what information is available, and the associated legal obligations.

Public communications leading up to and during implementation will also reiterate the reasons why checking SafeScript before issuing a prescription or dispensing a medicine is necessary in order to maximise the benefits of SafeScript in reducing harms and deaths from high-risk prescription medicines.

Compliance will also be promoted by working with key medical and pharmacy groups, such as the Royal Australian College of General Practitioners and the Pharmaceutical Society of Australia, to incorporate the practice of checking SafeScript in clinical care guidelines. Through this, it is envisaged that the act of checking SafeScript before issuing a prescription or dispensing a medicine will be considered as a routine and essential part of a patient assessment to ensure safe patient management and the appropriate use of prescription medicines.

5.6.2 Determining non-compliance

SafeScript will capture information necessary to monitor compliance with the requirement to check the system when use of SafeScript becomes mandatory. The main pieces of information required to detect whether health professionals have used SafeScript are:

- A record of issuing a prescription or dispensing a medicine, and
- A record of when the patient record was viewed by a prescriber or pharmacist.

SafeScript will automatically collect prescription records from pharmacy dispensing software. When a pharmacist dispenses a medicine using the pharmacy's dispensing software, the record created will be transferred from the pharmacy software to SafeScript, i.e. no additional step is required by pharmacists to enter records directly into SafeScript. Pharmacists will not have the option to determine which records will be transmitted to SafeScript.

While prescribers are not prevented from issuing a prescription and pharmacists are not prevented from dispensing a medicine if they decide not to check SafeScript, an audit trail will be created each time a patient record is viewed. Instances of prescribers and pharmacists not checking SafeScript can be detected through routine audits, or when conducting compliance investigations.

Specifically, when a prescription is issued or medicine dispensed, the record can be matched against the audit trail history to determine whether the prescriber and pharmacist had checked SafeScript prior to the prescribing and dispensing of the medicine.

The functionality of SafeScript will include a business analytics platform to enable DHHS to detect instances of high risk prescribing or supply. This will enable DHHS to prioritise matters for investigation.

SafeScript will be able to detect instances when a patient has obtained the same prescription or medicine from multiple prescribers or pharmacies and issue an alert to DHHS and to health professionals.

DHHS will be able to view the records and determine whether the prescribers and pharmacists had checked SafeScript at the point of issuing a prescription or dispensing a medicine.

5.7 Enforcement

Upon commencement of mandatory use, compliance activities will be undertaken to enforce the mandated use of SafeScript. The powers in the Act enable DHHS to enforce the following requirements:

- Data source entities must provide information to SafeScript.
- Prescribers (medical practitioners and nurse practitioners) must check SafeScript before prescription or supply of monitored supply poisons.
- Pharmacists must check SafeScript before supply of monitored supply poisons.
- Persons who are not authorised to access SafeScript must not do so.

These penalties have been enacted to ensure that SafeScript is used properly in order to meet the objectives of this initiative. Each breach of these requirements carries a penalty of 100 penalty units as stated in the Act.

The enforcement activities carried out by DHHS relating to the use and operation of SafeScript will align with its current risk-based approach for managing compliance and enforcement activities. Specific to SafeScript, they may include the following:

1. Where failure to comply with the requirements to check SafeScript occurs, prescribers and pharmacists will be counselled and provided with information and education to help alter their behaviour. This is intended to reinforce the legal obligations to check SafeScript as well as the potential risks of inappropriate issuing of a prescription or dispensing of a medicine if the system is not utilised.
2. If the prescriber's or pharmacist's failure to check SafeScript before issuing a prescription or dispensing a medicine has placed the community at significant risk or resulted in patient harm, such as an oversupply of medicines contributing to an overdose, DHHS may decide to initiate prosecution proceedings and/or may refer the matter to the relevant registration board (e.g. the Australian Health Practitioner Regulation Authority) for further investigation and action.
3. Should a prescriber or pharmacist repeatedly fail to check SafeScript despite repeated efforts from DHHS to provide counselling and education, DHHS may decide to initiate prosecution proceedings. If found guilty, the prescriber or pharmacist may incur penalties.

The extent of the enforcement that DHHS takes will be in proportion to the seriousness of the infraction. Factors that come into the decision include: the risk of harm to health and the likelihood of non-compliance continuing. Enforcement actions can vary from, giving advice and guidance to instigating legal prosecution of serious and deliberate contraventions.

The costs associated with enforcement activities will largely depend on the level of non-compliance. However, it is difficult to estimate what non-compliance will be. DHHS is not aware of any benchmarks to indicate potential non-compliance, noting that the Tasmanian system is non-mandatory.

6 Evaluation strategy

This chapter describes the mechanisms that will enable the Government to measure and demonstrate how, and how well, SafeScript has worked in practice.

6.1 Overview

In accordance with good regulatory practice, the Government is developing an evaluation strategy to measure the efficiency and effectiveness of the proposed Regulations, and SafeScript more generally. The evaluation strategy will be refined during 2018 and prior to SafeScript commencing, however the following section sets out DHHS's current thinking on the evaluation approach.

DHHS proposes that the evaluation strategy for SafeScript will comprise four distinct elements:

1. Baseline – gathering a range of data on current outcomes in order to provide a baseline for future comparisons
2. Implementation – continuing evaluation during the implementation phase to 'fine tune' the SafeScript rollout
3. Ongoing monitoring via the collection of a range of data on an annual basis
4. Three-year review – a more comprehensive mid-term review after three full years of SafeScript to determine whether it is achieving its objectives

DHHS will be responsible for evaluating and reporting on the effectiveness of SafeScript.

The information below outlines the purpose of each stage of the evaluation strategy, and data to be collected as part of the strategy.

6.2 Baseline

The purpose of the first stage is to establish the baseline of information that will enable the evaluation of SafeScript once it has been introduced. It would therefore be undertaken before the introduction of SafeScript.

Key parts of this review would include gathering existing information from databases particularly focused on harms related to monitored medicines. DHHS will gather information from the current S8 permit system, and other existing relevant health data sources, such as hospital admission data, ambulance data and PBS data.

The baseline will include indicators of the effectiveness and efficiency of the current S8 permit system and the current level of harm caused by S8 and S4 poisons and other medicines in the Victorian community, including those not being monitored by SafeScript.

Given that SafeScript will commence in 2018-19, it is proposed that baseline data will primarily be gathered for the 2017-18 year.

6.3 Implementation stage evaluation

As SafeScript will be implemented in a phased manner, this provides the opportunity to rapidly evaluate outcomes in early phases and then adapt subsequent phases of the rollout to reflect learnings and outcomes to date.

Key elements of this stage of the evaluation will include examining such things as

- What is the uptake of registration by prescribers and pharmacists in the pilot group?
- Are prescribers and pharmacists in the pilot group accessing SafeScript appropriately?
- Are there any major issues in using SafeScript?
- Do any barriers exist that will impair the use of SafeScript?
- Are there indications that SafeScript has significantly changed demand for other Government services, such as alcohol and drug treatment and support?

This information will ensure that the system can be refined as the system is progressively rolled out state-wide. It is anticipated that the above issues may vary depending on the stage of the rollout and by region. Any differences would be assessed during the implementation process and, where required, workforce training may be concentrated in areas where need is identified.

6.4 Public awareness campaign evaluation

The effectiveness of public awareness campaign will be measured through survey analysis involving participants from the general public, including consumers and health professionals in Victoria.

The first survey will be conducted before the start of the campaign to measure current awareness, attitudes and beliefs related to high-risk prescription medicines. This survey is planned for early 2018. The second survey is planned for mid-2019, after the campaign is completed, and will be based on the same questionnaire.

The results of the two surveys will be analysed and compared to provide data to measure the changes and evaluate the effectiveness.

6.5 Ongoing evaluation

Once SafeScript is in place across the state, DHHS will undertake ongoing evaluation of the system. The purpose of this would be to ensure that SafeScript is operating efficiently and effectively at a state-wide level.

This would provide DHHS with a clear indication of whether SafeScript is achieving the intended objectives and benefits, as well as whether there are any unintended consequences that need to be managed. By this stage, SafeScript would be available to all prescribers and pharmacists, meaning that this review will capture a broader range of users than during the implementation stage.

This evaluation will be based around the data and performance indicators set out in section 6.6.1 below, which will be collected (at least) on an annual basis.

6.6 Three-year review

It is proposed that a formal mid-term review of the Regulations be conducted in 2023/24 – once data for three full years of SafeScript operation is available. The purpose of the three-year review is to assess whether:

- SafeScript has, as a whole, achieved the intended objectives and benefits,
- The costs and/or burdens placed on health professionals are higher or lower than anticipated, and make any adjustments to the system if necessary.
- There are any unintended costs, issues or other consequences of SafeScript that need to be addressed or managed.

This information will enable DHHS to consider whether any adjustments to the Regulations are desirable.

Key parts of this review would include gathering existing publicly available information from various sources, utilising the data captured by SafeScript, and conducting surveys and/or focus groups of practitioners. A survey and/or focus group on broader groups indirectly affected by SafeScript may also be useful, such as patients and referral services.

The questions to be considered as part of the three-year review are:

- Has introducing the system aided the clinical decision making process (including SafeScript itself as well as the accompanying workforce development initiatives)?
- Has there been a net benefit associated with introducing SafeScript, and if so how large is this benefit?
- Is SafeScript efficient for users?
- Has SafeScript achieved its objectives:
  - Does it promote safe supply, prescription and dispensing practices?
  - Has it reduced harm from monitored poisons and other high risk medication?
  - Does it facilitate evaluation and research into monitored poisons?

Specifically regarding the regulations, the three year review will also consider:

- Whether the scope of medicines monitored in SafeScript is appropriate.
- Whether there has been observable substitution towards other potentially harmful prescription medications
- Whether there are other settings or circumstances that should be exempt from mandatory use, or whether any of the existing exceptions should be withdrawn.

The three year review will include revisiting the model used to calculate the benefits and costs set out in Chapter 4 and using actual data to assess outcomes.

6.6.1 Key performance indicators for the objectives of SafeScript

Below is a list of data and KPIs that will allow DHHS and the Victorian Government to better understand and report on whether the objectives of the legislative change are being met. This data will support the ongoing and three-yearly review processes.

Some of the KPIs listed below are relevant for multiple objectives, with possible sources for Victorian data in brackets. These KPIs were based on consultations and the literature around prescription monitoring systems in other jurisdictions.

In some cases the performance indicators will not be definitive - that is, changes in outcomes may not be entirely attributable to SafeScript. For example, there may be changes in the number of patients supplied with S8 and monitored S4 poisons due to new treatment methods or drugs becoming available. Where possible, any

analysis of the effectiveness of SafeScript will need to take this into account. However, all other things being equal, the indicators below should provide a strong evidence base as to whether SafeScript has been successful.

Has SafeScript reduced harm from monitored poisons and other high risk medication?

- Number of deaths related to other prescription or illicit drugs (Coroners Prevention Unit)
- Number of S8 and monitored S4 poison-related ambulance attendances (Trends in Alcohol and Drug-Related Ambulance Attendances – Turning Point Alcohol and Drug Centre)
- Number of patients supplied with S8 and monitored S4 poisons (SafeScript)
- Number or percentage of prescribers and pharmacists that are registered to use SafeScript (SafeScript)
- Number of PBS prescriptions for other medicines that may be used to substitute monitored medicines (PBS data).
- Number of S8 and monitored S4 poison-related hospitalisations (Victorian Admitted Episodes Dataset)

Has SafeScript promoted safe supply, prescription and dispensing practices?

- Number of patients dispensed S8 and monitored S4 poisons (SafeScript)
- Number of PBS prescriptions for S8 and monitored S4 poisons (PBS data)
- Number of S8 and monitored S4 poison-related deaths (Coroners Prevention Unit)
- Average duration of treatment with S8 and monitored S4 poisons (SafeScript)
- Number of people receiving opioid replacement therapy (DHHS)
- Number of S8 and monitored S4 poisons that that Victorian patients are accessing interstate (SafeScript).
- Percentage of practitioners identified as engaging in unsafe, inappropriate or unlawful prescribing/dispensing (DHHS compliance audits).

These data sources may also be considered to help identify potential substitution to other medicines not included by SafeScript or other drug-related harms.

Has SafeScript facilitated evaluation and research into monitored poisons?

- Number of academic articles referencing SafeScript (Academic databases)

To improve the strength of the evaluation, it would be useful to compare the KPIs in Victoria not only to the baseline (2017/18) data where this is available (which may be the first year of data for indicators that rely on SafeScript), but also to those of other states. This would be done to establish a counterfactual: even if prescription medicine-related deaths were to rise after implementation of the RTPM system in Victoria, this would not necessarily mean that the initiative had failed, as deaths may have been even higher if the initiative were not in place. For example, if prescription medicine overdose deaths increase by 5% in Victoria while they increased by 20% in the rest of Australia, this may indicate that the initiative may be realising some of its expected benefits.

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Appendix A: Key parameters

Key parameters and assumptions

Table A.1 outlines the key assumptions that underlie the modelling results for the cost of the choice of medicine coverage. It is important to note that there is inherent uncertainty in the true values for each input, and where this is present conservative figures that overstate the costs have been chosen.

Table A.1: Key parameters, their value, and source.

Formulae with square brackets indicate that the given parameter is composed of other parameters.

#	Parameter	Value	Source
1	Victorians identified as obtaining high-risk medicines at levels beyond therapeutic need in 2011/12[8]	986	Number of Victorians identified by the Medicare Prescription Shopping Programme.
2	Prescriptions per person identified as obtaining high-risk medicines at levels beyond therapeutic need in 2011/12	100	Number of prescriptions needed per year to meet Medicare criteria for obtaining high-risk medicines at levels beyond therapeutic need.
3	Prescriptions for high-risk medicines identified as being beyond what is needed by a patient for therapy	96,800	[1]*[2] (Estimate based on Medicare criteria for prescription obtaining high-risk medicines at levels beyond therapeutic need).
4	GP hourly wage (2016-17)	$149.30	Calculated based on the MBS rebate received for a standard consultation (Item 23), and assuming a rate of 4 consultations per hour.
5	Pharmacist hourly wage (2017)	$53.11	Simple average of different levels of pharmacist wages from the FairWork award schedules, multiplied by 1.75 to account for overheads.

[8] This is the only year for which an estimate exists – and is considered to be a conservative estimate (see Chapter 2.1.3).

6	Wage inflation	2.5%	Reserve Bank of Australia wage forecasts.
7	Number of S8 prescriptions in 2011/2012	1,518,477	Medicare Statistics on Medicines.
8	Percentage of prescriptions obtained in excess of therapeutic need or for non-therapeutic purposes	6.37%	[3]/[7]
9	Percentage of inappropriate prescriptions identified by prescribers	50%	Assumption: we assume that 50% of prescriptions are identified by prescribers (rather than pharmacists) as inappropriate and therefore not issued and presented to a pharmacist. During the initial 18 month transition period before use of SafeScript becomes mandatory, this share would likely be lower (since checking is non-mandatory for prescribers), however this was not factored in to the analysis as this figure is unknown.
10	Percentage of people seeking prescriptions beyond therapeutic need identified, resulting in an intervention	100%	Assumption: we assume (conservatively) that all instances of people obtaining prescriptions beyond therapeutic need are identified, resulting in an intervention. This overstates the costs associated with intervention as we would in fact expect fewer than 100% of instances to be identified. This variable increases total costs more than benefits, therefore a higher number is more conservative.
11	Percentage of interventions where treatment is received through AOD treatment services	25%	Source: NDARC (2014).
12	Pharmacist time to check SafeScript	1 minute	Estimate by Deloitte Access Economics. This is an upper bound on the time that it would actually take to check SafeScript.
13	Pharmacist time cost to check SafeScript	$0.89	[12]*[5]/60
14	Prescriber time to check SafeScript	1 minute	Estimate by Deloitte Access Economics. This is an upper bound on the time that it would actually take to check SafeScript.
15	Prescriber time cost to check SafeScript	$2.49	[14]*[4]/60

16	Cost of intervention using AOD treatment services in 2017	$4,559.19	Source: DHHS. The cost of intervention is $2,383 which is based on the weighted average cost for a course of treatment. This is then multiplied by 1.93 which is the average number of courses of treatment per patient.
17	Cost of intervention using primary care services (2016-17)	$108.04	MBS Benefit for a GP consultation spanning over 40 minutes (Item 44). Source: MBS Statistics.
18	Inflation rate	2.5%	RBA inflation target.
19	GP visits per person classified by DHS as prescription shopping	24	DHS's definition of prescription shopping has a minimum of 24 GP visits per year (see Box 4.3).
20	ED visits per overdose death	32	CDC (see Box 4.2).
21	Hospital admissions per overdose death	10	CDC (see Box 4.2).
22	GP consultation time	15 minutes	Average GP consultation time found by Britt, Valenti, & Miller (2014).
23	Cost of GP consultation	$37.33	[4]/4
24	Cost of ED presentation	$895.91	Detailed in Section 4.2.2.3.
25	Value of statistical life (2014)	$4.2 million	Standard value of statistical life for use in economic evaluation as set out by the Department of Prime Minister and Cabinet.
26	Percentage reduction in adverse events	12%	Evidence from the US which showed state-based mandatory RTPM implementations had reduced deaths by 12% (Dowell, Zhang, Noonan, & Hockenberry, 2016). During the initial 18 month transition period before use of SafeScript becomes mandatory, the reduction in adverse events is estimated (conservatively) to be 3.5%.
27	Cost of hospital admission	$7,739.51	Detailed in Section 4.2.2.2.
28	Share of harm due to S4 poisons	67%	Victorian Coroner (Dwyer J. , 2016)
29	Share of harm due to S8 poisons	33%	Victorian Coroner (Dwyer J. , 2016)

30	Time to register on SafeScript	15 minutes	Estimate, Deloitte.
31	Time to train for SafeScript	30 minutes	Estimate, Deloitte.
32	Prescriber cost to train and register (2015)	$111.98	[4]/60*([30]+[31])
33	Pharmacist cost to train and register (2017)	$39.83	[5]/60*([30]+[31])
34	SafeScript implementation fixed cost	$29.5 million	Victorian Government.
35	Ongoing SafeScript costs (per year)	$2.817 million	DHHS.
36	Discount rate	4%	Suggested rate in the Victorian Guide to Regulation.
37	Clinician uptake rate of SafeScript (for the 18 month transition period before use of SafeScript becomes mandatory)	4%	This was the system uptake rate that was observed in Tasmania when an RTPM system was initially introduced. As such, checking and intervention costs are reduced by 96%, compared to a full uptake, during this period.
38	Inappropriate prescriptions prevented during the 18 month transition period	4%	This assumes that 4% of "inappropriate prescriptions" are identified and prevented during the first 18 months before use of SafeScript becomes mandatory. This is based on the Tasmanian uptake rate.

Assumed growth rates

Table A.2 outlines the assumed growth rates used in the projections that inform the modelling undertaken in the RIS. It is important to note that projections and forecasts are uncertain (and increasingly so for later years of the forecast period) and many of the growth rates projected are sensitive to policy changes (e.g. the rescheduling of PBS medicines).

Different periods may be used to calculate the growth rates for the projections used in the analysis. This is because changes in the trend, known as structural breaks, can alter the useful range used to inform projections. DHHS considers these historical growth rates as appropriate to use for future projections, since they reflect ongoing macro drivers such as population and economic growth, and also reflect specific trends relating to the increased supply of, and harm caused by, prescription medications.

Table A.2: Growth rates used in the analysis as well as the calculation method used

Growth rate	Value	Calculation method
S4 PBS prescriptions	1.60%	Average growth rate 2001/02-2016/17
S4 PBS expenditure	1.73%	Average growth in PBS expenditure 2006/07-2016/17
S8 PBS prescriptions	2.44%	Average growth rate 2014/15-2016/17
S8 PBS expenditure	0.04%	Average growth in PBS expenditure 2001/02-2016/17
Pharmacist numbers	2.85%	Average growth rate 2011/12-2016-17
Prescriber numbers	2.86%	Average growth rate 2011-2015
Deaths from pharmaceutical medicines	3.26%	Average growth rate 2009-2016

Limitation of our work

General use restriction

This report is not intended to and should not be used or relied upon by anyone other than the Victorian Department of Health and Human Services and Deloitte accepts no duty of care to any other person or entity. The report has been prepared for the purpose of assessing the impact of the proposed Drugs, Poisons and Controlled Substances Amendment (Real-time Prescription Monitoring) Regulations 2018. You should not refer to or use Deloitte's name or the advice for any other purpose.

This report presents the best information currently to DHHS and Deloitte. Information obtained by DHHS through public consultation on this report, as well as the result of subsequent evaluation of SafeScript, will be used to improve this evidence base.

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