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| SafeScript  |
| Frequently Asked Questions – for health professionals |

## General questions about SafeScript

#### What is SafeScript?

SafeScript is computer software that allows prescribing and dispensing records for certain high-risk medicines to be transmitted in real-time to a centralised database which can then be accessed by doctors and pharmacists during a consultation.

SafeScript provides prescribers and pharmacists with a clinical tool to make safer decisions about the prescribing or dispensing of high-risk medicines, and facilitate the early identification, treatment and support for patients who are developing signs of dependence.

After a successful study area focussed on the Western Victoria Primary Health Network region, SafeScript was implemented across Victoria from 1 April 2019.

#### Why is SafeScript necessary?

The harms and increasing number of deaths from prescription medicines are a major public health concern.

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| Deaths in Victoria | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 |
| Pharmaceutical medicines | 303 | 312 | 316 | 356 | 381 | 414 |
| Illicit drugs | 130 | 163 | 164 | 227 | 263 | 271 |
| Road toll | 282 | 243 | 248 | 252 | 290 | 258 |

In 2017 there were 414 Victorian drug overdose deaths involving pharmaceutical medicines, higher than the number of overdose deaths involving illicit drugs (271), and higher than the road toll (258). In 2016-17, there were almost as many ambulance callouts relating to pharmaceutical medicines (10,517) than for illicit drugs (11,097).

#### What medicines are monitored through SafeScript?

Based on the latest international and local research and recommendations from an expert advisory group, the system monitors prescription medicines that are causing the greatest harm to the Victorian community.

Medicines that are monitored include:

* all Schedule 8 medicines
* benzodiazepines, such as diazepam
* ‘Z-drugs’ (zolpidem, zopiclone)
* quetiapine
* codeine containing products

SafeScript monitors all prescriptions for these medicines regardless of whether they receive a PBS subsidy or are private, non-PBS prescriptions.

#### How does SafeScript collect prescription information?

The data required for SafeScript is collected automatically from the Prescription Exchange Services (PES) which currently support the electronic transfer of prescriptions from medical clinics to pharmacies.

When a prescription is issued at a medical clinic or dispensed at a pharmacy, the PES sends a record of the prescription in real-time to SafeScript. No additional data entry is necessary to record a prescription in SafeScript.

#### Who has access to patient records in SafeScript?

Doctors, nurse practitioners and pharmacists have access to SafeScript to view records of all high-risk medicines that have been supplied to patients under their care. This enables health professionals to make safer and more informed clinical decisions and facilitates the co-ordination of treatment and communication by giving them visibility of all clinicians involved in the patient's care.

Authorised Department of Health and Human Services staff will also access SafeScript as part of their regulatory role in ensuring the safe supply of medicines in the community.

## Using SafeScript in clinical practice

#### When am I permitted to access a patient record in SafeScript?

#### Patient records in SafeScript may only be lawfully accessed when you are involved in that patient’s medical care and in the context of the medicines which are monitored.

#### If you do access a patient's record in SafeScript, you will need to make sure you can substantiate this access in your capacity as their registered health practitioner.

#### The following is a non-exhaustive list of circumstances where accessing patient records in SafeScript would be permitted in law:

* when prescribing or supplying a medicine to the patient,
* when reviewing the patient’s medication history as part of a patient consultation (e.g. when a doctor takes a patient history or a pharmacist conducts a medication review), or
* when discussing the patient’s medication history with other registered health practitioners who are involved in that patient’s care.

#### You must not use the information in SafeScript for any other purpose. Any other purpose may include (but is not limited to) marketing or commercial purposes.

### Do I need to seek patient consent to access SafeScript?

Doctors, nurse practitioners and pharmacists who are involved in the care of a patient are authorised under law to access that patient’s record in SafeScript, without express permission from the patient, for the purposes of ensuring the patient’s safety from prescription medicine related harm.

This authorisation is made under the *Drugs, Poisons and Controlled Substances Act 1981*.

#### How do I view records from my medical clinic or pharmacy?

All clinicians can access the [SafeScript portal](http://www.safescript.vic.gov.au) <www.safescript.vic.gov.au> on their computer or via a tablet or mobile device.

SafeScript can also be integrated with your clinical software to save you time. Pop-up notifications appear within seconds of prescribing or dispensing a high-risk medicine to inform you whether there are records in SafeScript requiring your review. A click on the notification takes you directly to the patient's SafeScript record.

See videos and quick reference guides about integrating your clinical software on the [Setting up and accessing SafeScript page](https://www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript/access-and-setup) at: <www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript/access-and-setup>.

#### What do pop-up notifications in my software and alerts in SafeScript mean?

When using SafeScript, it is important to differentiate between notifications and alerts.

**Notifications** are the red, amber or green messages that pop-up on a prescriber or pharmacist’s screen when they are prescribing or dispensing a medicine monitored in SafeScript. These notifications are designed to quickly and clearly signal to the prescriber or pharmacist if checking the patient’s record in SafeScript is required.

**Alerts** exist within the SafeScript portal and indicate that the dispensing history for a patient has met certain criteria for high-risk circumstances. Clinicians will be prompted to consider this information as part of their clinical decision-making.

#### What are the red, amber and green pop-up notifications that display in my software?

A **red notification** will appear when there is a clinical alert relating to the prescribing/dispensing history of a patient. These alerts include:

* **Multiple provider episodes:** When prescriptions from 4 or more prescribers/medical practices have been recorded in SafeScript within the last 90 days.
* **High-risk drug combinations**: When prescriptions for certain drug combinations have been recorded in SafeScript within the last 90 days.
	+ - Methadone + a benzodiazepine
		- Methadone + a long-acting opioid
		- Fentanyl + a benzodiazepine
		- Fentanyl + a long-acting opioid
	+ **Opioid dose threshold**: When the daily morphine equivalent dose (calculated based on an average over the last 90 days) exceeds 100mg MED daily (i.e. a high-risk dose).

When use of SafeScript becomes mandatory, clinicians will be required to click on the red notification to review the patient history to assess whether it is safe or appropriate to prescribe or dispense a medicine.

**An amber notification will appear in the following situations:**

* When prescriptions for a monitored medicine in the last 6 months have been issued by more than one prescriber/medical practice, or 4 or more pharmacies.
* When the daily morphine equivalent dose (calculated based on an average over the last 90 days) is between 50mg and 100mg MED daily (i.e. a medium risk dose)

When use of SafeScript becomes mandatory, prescribers/pharmacists will be required to click on the notification to review the patient history to assess whether it is safe or appropriate to prescribe/dispense a medicine.

 **A green notification will appear in the following situations:**

* + When there has not been a prescription issued or dispensed for a monitored medicine in the last 6 months, or
	+ When prescriptions for a monitored medicine in the last 6 months have been issued by the same prescriber, and there are no clinical alerts

When use of SafeScript becomes mandatory, clinicians will not be required to click on the notification to review the patient history.

#### Does an alert in SafeScript mean I am not allowed to prescribe or dispense a medicine?

An alert does not mean that you are not allowed to prescribe or dispense a medicine, but it indicates that some clinical risk has been identified which you need to review and manage appropriately.

SafeScript does not instruct you on what to do or decide whether a medicine should or should not be prescribed to your patient. This remains your clinical decision to determine whether the medicines prescribed continue to be the safest and best option for your patient’s medical needs.

Should you decide that a medicine is no longer the safest treatment, you are reminded that good clinical practice involves ensuring that appropriate continuity of care is provided for your patient. Abruptly discharging the patient from your care or abruptly stopping treatment in patients who have been taking high-risk medicines over a long period of time may be contrary to patient safety. There may be implications to discontinuing some medicines too quickly. For example, sudden withdrawal of benzodiazepines may result in rebound insomnia or anxiety, or at worst, seizures.

Medical practitioners and pharmacists are also reminded of their responsibilities as part of their professional registration, contained within their code of conduct. It is important that all patients receive the same standard of care, remembering that anyone can develop a dependency on prescription medicines.

Clinicians are strongly encouraged to complete the comprehensive training provided as part of SafeScript implementation, which has a focus on enhancing clinical and counselling skills. When you identify a high-risk circumstance in SafeScript, this training will give you the confidence and skills to enable you to continue to provide safe and appropriate ongoing care to your patient. More information about the training available can be found at the [SafeScript Training Hub](https://vtphna.org.au/safescript-training-hub/) <https://vtphna.org.au/safescript-training-hub/>.

#### I prefer keeping paper patient files and I handwrite prescriptions. How can I access SafeScript?

While SafeScript has been designed to integrate with clinical workflows for clinicians using prescribing software, prescribers are not required to use medical practice software in order to access SafeScript.

Access is still available at all times via the secure [SafeScript portal](file:///C%3A%5CUsers%5Ccden2005%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CKSIH0ANU%5CSafeScript%20portal) <https://www.safescript.vic.gov.au> for prescribers who write paper prescriptions. The portal is also available on mobile or tablet devices.

#### What support is provided to patients and health professionals for the implementation of SafeScript?

SafeScript is accompanied by a range of initiatives to support and prepare patients and health professionals for its implementation. These include:

* A public awareness campaign aimed at improving understanding of the risks associated with some prescription medicines. Brochures about SafeScript for patients have been supplied to pharmacies and medical clinics. To order more brochures, please email safescript@dhhs.vic.gov.au.
* SafeScript GP Clinical Advisory Service isa peer-to-peer service helping GPs to support patients with prescription medicine concerns and complex needs (**1800 812 804**). More information can be found at the [GP Clinical Advisory Service website](https://dhhsvicgovau-my.sharepoint.com/personal/catherine_dennehy_dhhs_vic_gov_au/Documents/GP%20Clinical%20Advisory%20Service%20website) <https://www.dacas.org.au/clinical-resources/clinical-advisors>.
* Accredited SafeScript training available online, covers planning for consultations, alternative management options and having challenging conversations. Online training can be accessed at the [SafeScript Training Hub](https://vtphna.org.au/safescript-training-hub/) <https://vtphna.org.au/safescript-training-hub/>.
* Secondary consultation services are also available to medical practitioners through Reconnexion, specialising in anxiety disorders, depression and benzodiazepine dependency. Reconnexion also offers counselling services for patients and can be reached on 1300 273 266 or at [www.reconnexion.org.au](http://www.reconnexion.org.au).
* The SafeScript Pharmaceutical Helpline is ready to respond to patients with concerns about their use of high-risk medicines. This line is staffed by nurses and trained counsellors and is available 24 hours a day. Patients can reach the Helpline by calling 1800 737 233.

## Mandatory use

#### Will the use of SafeScript be mandatory?

It will be mandatory to check SafeScript prior to writing or dispensing a prescription for a high-risk medicine from April 2020. This follows worldwide best practice, as mandatory systems adopted in other countries have shown to provide greater reduction in harms from high-risk prescription medicines.

There will be exceptions in some circumstances, including when treating patients in hospitals, prisons, police gaols, aged care and palliative care.

#### Are there penalties for clinicians if they fail to check SafeScript from April 2020?

The *Drugs, Poisons and Controlled Substances Act 1981* specifies penalties that can be imposed on clinicians if they do not take all reasonable steps to check SafeScript when prescribing or dispensing a high-risk medicine.

The penalties of 100 penalty units are identical to the existing penalties in drugs and poisons legislation for failing to apply for a treatment permit when prescribing Schedule 8 medicines to patients. These penalties have been in place under drugs and poisons legislation in Victoria since the early 1960s.

While the Act has provisions to prosecute for failure to comply with these requirements, non-compliance is assessed within a risk-based framework that focusses on conduct that poses the most significant risks of harm to patients and practitioners who have repeatedly failed to comply with SafeScript requirements.

The department utilises a range of compliance tools, including education and counselling, to assist practitioners to meet their regulatory obligations, and takes individual circumstances into account before any consideration is made on a decision to initiate prosecution.

**What does taking “all reasonable steps” to check SafeScript mean?**

From 1 April 2020, the *Drugs, Poisons and Controlled Substances Act 1981* will require prescribers and pharmacists to take all reasonable steps to check SafeScript when prescribing or supplying a high-risk medicine.

There may be circumstances where clinicians may not be able to check SafeScript but they consider it necessary to prescribe or supply a high-risk medicine. The phrase “all reasonable steps” takes into consideration what measures were taken by a clinician to attempt to satisfy this requirement.

Examples include:

* Contacting the department to enquire about a patient history in SafeScript
* Contacting the pharmacy to enquire about the patient history in SafeScript
	+ If access to SafeScript is temporarily unavailable, prescribing or supplying limited quantities and checking SafeScript at the next available opportunity

Clinicians who do not check SafeScript simply because they have not registered or have not arranged access to a computer, and do not consider other measures to establish the patient’s history in SafeScript, are unlikely to satisfy this requirement.

## Privacy and data security

### How is patient privacy protected under law?

There are offences and strict penalties under the *Drugs, Poisons and Controlled Substances Act 1981* for improper or unauthorised use of SafeScript.

A log is created each time a record is viewed in SafeScript and this is monitored by the Department of Health and Human Services. If inappropriate use is detected, health professionals may face penalties under Victorian law and the matter may be referred to the Australian Health Practitioner Regulation Agency for further investigation.

Health professionals must always adhere to privacy requirements set out in the *Health Records Act 2001* and *Privacy Act 1988* when handling patients’ health information. The Health Privacy Principles and Australian Privacy Principles specify the circumstances where health professionals can access, collect, use or disclose health information about an individual.

A Privacy Impact Assessment has been undertaken to ensure the implementation of SafeScript is compliant with privacy laws.

### How does SafeScript keep records secure?

SafeScript has been built to the Victorian Protective Data Security Standards, which provide a set of criteria for the consistent application of risk managed security practices across Victorian Government Information. The Victorian Protective Data Security Standards are consistent with Commonwealth Government security measures, including the Australian Signals Directorate’s Information Security Manual.

SafeScript has been independently security audited as well as security tested to this standard.

#### Data encrypted in transit and at rest

Data transmitted between medical practice systems, pharmacy systems and the SafeScript database is encrypted at all times and occurs through a secure, encrypted internet connection. Data stored in the SafeScript database is also encrypted at all times.

#### Multi-factor authentication

SafeScript also utilises contemporary security measures to safeguard data against unauthorised access. Health professionals will be required to use multi-factor authentication (a username/password + PIN) in order to access the system.

#### Penetration testing

The security of the system is routinely tested and reviewed to ensure data stored in SafeScript remains protected.

## Other questions

#### How does this initiative impact current arrangements for prescribing these medicines in Victoria?

As SafeScript now provides clinicians direct access to prescription histories of their patients for high-risk medicines, there is reduced reliance on the Schedule 8 permit system to assist in the co-ordination of care. This means that some of the Schedule 8 permit requirements for prescribers have been reduced when they check SafeScript before prescribing a Schedule 8 medicine.

Further information on permit requirements is available on the [Medicines and Poisons Regulation website](https://www2.health.vic.gov.au/public-health/drugs-and-poisons/patient-schedule-8-treatment-permits) <https://www2.health.vic.gov.au/public-health/drugs-and-poisons/patient-schedule-8-treatment-permits>.

### Will data be used for research purposes?

De-identified data in SafeScript may be used by the Victorian Government to inform service planning and policy decisions to improve healthcare for the Victorian community.

The harms from prescription medicines is a growing public health issue. Data in SafeScript may also be published at an aggregate population level to respond to the increasing research interest in understanding the level and trends of prescription medicine usage.

All data used for research and evaluation purposes will be in accordance with the requirements in the *Health Records Act 2001* and the appropriate Human Research and Ethics Committee standards.

#### Why can’t the My Health Record be used for real-time prescription monitoring?

The My Health Record is a patient-controlled summary of a patient’s health record, in which patients can choose what is included and who can view their medication history. SafeScript is different because it allows doctors and pharmacists involved in a patient’s care access to a complete record of high-risk medicines that have been supplied.

Patients are not be able to opt-out or restrict what medication history can be viewed in SafeScript. This is necessary to ensure a comprehensive medication history can be captured to allow health professionals to make safer clinical decisions and reduce the harms caused by high-risk medicines.

#### Where can I get further information?

Further information is available on the [SafeScript website](http://www.health.vic.gov.au/safescript/) at <www.health.vic.gov.au/safescript>.

The SafeScript General Enquiries team can be contacted on 03 9096 5633 or via email <safescript@dhhs.vic.gov.au>.