Regulation to support Real Time Prescription Monitoring (RTPM)

Introduction

What is Real Time Prescription Monitoring?

Real Time Prescription Monitoring (RTPM) is a national digital health system established by the Commonwealth Government that can provide doctors and pharmacists involved in your care with a comprehensive history of the high-risk medicines such as opioids and benzodiazepines you have been prescribed and dispensed. This information will help your doctor and pharmacist to make safer clinical decisions and will also help them to identify circumstances where you may be receiving potentially harmful medicines beyond medical need.

The Commonwealth Government established the National Data Exchange (NDE) and has provided funding for each state and territory to build their own RTPM database which will interact with the NDE.

RTPM is already operational in Victoria under the name SafeScript and most other States and Territories are in the process of planning and rolling out their own RTPM solutions.

NSW will introduce regulations to support the use of RTPM via an amendment to the *Poisons and Therapeutic Goods Regulation 2008* and the Ministry of Health is seeking feedback from the public on the proposed amendments.

This Consultation Paper provides more information about RTPM to assist you should you choose to provide feedback to the Ministry of Health.

Why is RTPM being implemented?

Prescription medicines can provide relief from the pain of an accident or injury, surgery or the symptoms of anxiety, sleep disorders and more. However, some prescription medicines can cause dependence and can become harmful.

The misuse of high-risk prescription medicines is a major public health issue. In 2018 there were 1556 unintentional (and therefore avoidable) drug-induced deaths in Australia. 457 (29%) of unintentional drug-induced deaths involved pharmaceutical opioids; and 648 (42%) involved benzodiazepines.

Health Ministers from the Commonwealth and all states and territories have agreed to implement national real time prescription monitoring as part of the solution to help save lives and reduce harm in the community.

What medicines will be monitored?

Prescription medicines that are causing the greatest harm, through overuse or non-medical use, to the NSW community will be monitored through RTPM.

An expert panel of medical advisors and researchers will determine which medicines should be included in the list of medicines to be monitored in RTPM (monitored medicines). This will be based on the latest international and local research.

The list of monitored medicines is not the subject of this consultation however for completeness and to enable meaningful feedback on the proposed amendments to the Regulations, the list will likely include:-

- Any substance in Schedule 8 (including opioids, psychostimulants, some cannabis-based medicines and some benzodiazepines)

- All benzodiazepines when included in either Schedule 4 or Schedule 8 (including alprazolam, bromazepam, clobazam, clonazepam, diazepam, flunitrazepam, lorazepam, midazolam, nitrazepam, oxazepam, temazepam, triazolam)

- codeine when in Schedule 4

- gabapentin

- pregabalin

- quetiapine

- tramadol

- zolpidem

- zopiclone

Other medicines may be added to the list of monitored medicines over time if there is evidence of an emerging risk that the overuse or non-medical use of a medicine is causing harm.

What information is to be recorded in RTPM?

When a doctor issues a prescription or a pharmacist dispenses a medicine to you, specific information is recorded. The NSW RTPM Database will collect this information when it relates to a 'monitored medicine' such as those listed above.

The information in the NSW RTPM Database will include:
- Patient name
- Patient address
- Details of monitored medicines supplied (name, strength, quantity)
- Prescriber and pharmacy details.

The NSW RTPM Database will NOT include:
- Other medical notes
- Information about medicines supplied to you that are not on the 'monitored medicines' list

Who has access to RTPM?

Doctors and other authorised prescribers such as nurse practitioners[1] and pharmacists who are directly involved in your care may view information about your prescription history for monitored medicines in RTPM to ensure the supply of prescription medicines is safe for you.

Authorised officers of the NSW Ministry of Health may also access RTPM as part of their regulatory role in ensuring the safe supply of medicines in the community.

Does RTPM prevent me from receiving my regular medicines?

RTPM will not instruct your doctor what to do or whether a medicine should or should not be prescribed for you. This clinical decision remains with them as they are best placed to determine whether the medicines prescribed to you remain the safest and best option for your health needs.

If you have been receiving the same medicines, or unsafe combinations, from more than one prescriber without each prescriber knowing, you could be at risk of harm. With access to this information, your doctor can consider discussing with you changes for your safety which might include better coordination of care, safely adjusting your medicine doses or recommending alternative approaches to managing issues such as pain, anxiety or insomnia.

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[1] A nurse practitioner is a registered nurse who has been endorsed as a nurse practitioner by the Nursing and Midwifery Board of Australia and has completed a Master's degree. Nurse practitioners practice at an advanced level and are authorised to prescribe scheduled medicines under the *Poisons and Therapeutic Goods Act 1966.*

Will doctors and pharmacists be given training to use RTPM?

As part of the roll out of RTPM, comprehensive training will be made available to doctors and pharmacists on how to use the system to ensure safer prescribing and dispensing as well as how to support the needs of patients. This training will give your doctor and pharmacist the confidence and skills to continue to provide you with the safest and most appropriate advice and ongoing care.

Your doctor will also be able to access a telephone advisory service for additional support and advice from health practitioners specialising in pain management, anxiety and other mental health conditions and substance use problems. This service can assist your doctor in ensuring that you continue to receive the safest and most appropriate ongoing care for your medical needs.

In addition, medical practices and pharmacies will be provided an information pack at the start of the roll out of RTPM to help prepare and set up the system in their practice.

Does my doctor or pharmacist need my permission to access my record in RTPM?

Doctors and pharmacists who are directly involved in your care will be authorised under law to access information about your prescription history for the monitored medicines in RTPM, without your express permission. This is for the express purpose of ensuring your safety when prescribing or dispensing high-risk prescription medicines.

How is my privacy protected under law?

Your personal and health information is protected by law. Both NSW and Commonwealth laws are based on privacy principles that require your personal information to only be collected, used and disclosed for authorised purposes; that your personal information is stored securely; and that you are provided with clear information about what personal information is held about you and how you might go about getting access to it or requesting that it be corrected where necessary.

In addition to these existing laws, there will be an offence and penalty under the *Poisons and Therapeutic Goods Regulation 2008* for any unauthorised access, use, or disclosure of information contained in the NSW RTPM Database.

As the system is electronic, it is much easier to audit who has accessed your records, and if they have done so inappropriately. An audit log will be created each time your details are viewed in RTPM and this will be monitored by the NSW Ministry of Health. If inappropriate use by a practitioner is detected, penalties may apply under NSW law and the matter may also be referred to the Medical, Nursing and Midwifery or Pharmacy Councils for investigation and possible disciplinary action.

How does RTPM keep my records secure?

RTPM is aligned with the national data security standards for government information and communications technology (ICT) systems set out by the Commonwealth Department of Defence to ensure your information is protected.

Data transmitted between medical practice systems, pharmacy dispensing systems and the RTPM database is encrypted at all times and will occur through a secure, encrypted internet connection. Data stored in the RTPM database will also be encrypted at all times.

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

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

Can I opt-out of RTPM?

RTPM is not an opt-out system.

The collection of prescription and dispensing records by RTPM for high-risk monitored medicines is necessary to provide doctors and pharmacists with access to a complete record of medicine supply to ensure patients do not receive more medicines than they medically need.

The *Poisons and Therapeutic Goods Regulation 2008* will require that records from electronic prescribing/dispensing systems for high-risk monitored medicines are to be provided to the NSW RTPM Database.

Can I request access to view my records in RTPM?

You have rights under both state and commonwealth privacy laws to access information held about you by your doctor, other healthcare practitioners or the government.

Should you wish to view records held about you in the NSW RTPM database, you may submit a request to the Ministry of Health. More information about how to submit this request will be provided to consumers before RTPM goes live in NSW.

Can I correct a record in RTPM if I believe it is incorrect?

It is important to remember that the RTPM NSW database contains a copy of information that is held in your doctor or pharmacist's clinical system.

RTPM does not alter records that are created in the source medical or pharmacy systems.

If you believe there is an error in a record, you may request the doctor or pharmacist involved in providing your prescription medicine to review their record. If their record is amended, the information will be automatically updated in RTPM.

If you would prefer, you may also submit a request to the Ministry of Health who will assist you to liaise with the doctor or pharmacist where the record was created. More information about how to submit this request will be provided to consumers before RTPM goes live in NSW.

Is RTPM the same as My Health Record?

RTPM and My Health Record are not the same.

My Health Record is a patient-controlled summary of your health records and includes a variety of medical history information including pathology results, GP authored health summaries, medicine information and hospital discharge summaries. You can choose what information is included in your My Health Record and who can view it.

RTPM will only contain information about 'monitored medicines' that are supplied to you. You are not able to delete or hide information contained in the NSW RTPM database.

RTPM is not integrated with My Health Record in any way and does not add any information to My Health Record.

Details of the Amendment to the *Poisons and Therapeutic Goods Regulation (2008)*

It is intended that the Regulation will—

1. establish the NSW RTPM database for the real time monitoring of the prescribing and supply of monitored medicines

2. establish a list of medicines that are to be monitored (monitored medicines)

3. authorise medical practitioners, nurse practitioners and pharmacists to provide specified information about prescriptions for monitored medicines to the NSW RTPM database. It is intended that this information will be provided to the database via a secure message using electronic prescribing or dispensing systems that are already in use by prescribers and pharmacists.

4. allow medical practitioners, nurse practitioners and pharmacists to view and use information contained in the NSW RTPM database for the purpose of making clinical decisions relating to the supply of high-risk medicines.

5. allow authorised officers of the NSW Ministry of Health to view and use information contained in the NSW RTPM database for the purpose of operating, maintaining, and improving the database, and regulating the prescribing, supply or use of monitored medicines

6. allow for the information in the NSW RTPM database to be visible in all State and Territory databases only if relevant laws are in place in other jurisdictions to protect the information

7. make unauthorised access, use, or disclosure of information in the NSW RTPM database an offence (Maximum penalty: 20 penalty units i.e. $2200)

8. allow exemptions under certain circumstances, such as exempting particular types of prescribers in some settings, for example, palliative care where monitored medicines are routinely used for symptom relief.

Information to be provided to RTPM by the prescriber and/or pharmacist

To ensure that information included in the NSW RTPM database is matched to the correct patient, it is critical that enough identifying information is provided by the prescriber or pharmacist to ensure accurate patient matching.

The Commonwealth has determined the minimum dataset required for accurate patient matching in RTPM and it includes the following:-

The patient's:

    a. full name, and

    b. date of birth, and

    c. gender, and

    d. Medicare number, if available, and

    e. Department of Veterans Affairs (DVA) number, if available, and

    f. Individual Healthcare Identifier assigned under the *Healthcare Identifiers Act 2010* of the Commonwealth, if available.

It is also critical that the information included in the NSW RTPM database correctly identifies the authorised prescriber, pharmacist and includes all relevant information about the monitored medicine.

The Commonwealth has determined the minimum dataset required for prescriber, pharmacist and medicine details and this includes:-

The prescriber's:

    a. full name, and

    b. Australian Health Practitioner Regulation Agency (AHPRA) registration number, and

    c. Pharmaceutical Benefits Scheme (PBS) prescriber number, and

    d. Healthcare Provider Identifier assigned under the *Healthcare Identifiers Act 2010* of the Commonwealth, if available.

The prescription details:

    a. the date on which the prescription is issued,

    b. the name and address of the patient,

    c. the name, strength and quantity of the medicine to be supplied,

    d. where relevant, the route of administration (if not readily apparent) of the medicine to be supplied,

    e. adequate directions for use,

    f. the maximum number of times the medicine may be supplied on the prescription,

The pharmacist's:

    a. full name, and

    b. AHPRA registration number, and

    c. Healthcare Provider Identifier assigned under the *Healthcare Identifiers Act 2010* of the Commonwealth, if available.

Additional details:

    a. the date on which the monitored medicine was supplied,

    b. the name and address of the pharmacy,

c. the prescription reference number (generated by the dispensing system)

d. the prescriber's PBS prescriber number.

Monitored Medicines List

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