

Electronic Recording and Reporting of Controlled Drugs



Context

Current regulations for Controlled Drugs (i.e. 'Dangerous' or 'Schedule 8' Drugs) are set out in relevant State and Territory medicines and poisons legislation. Common across all jurisdictions is a requirement of the pharmacist to record transactions for all Controlled Drugs in a register. Some jurisdictions also require regular reporting of all supplies by the pharmacy to the state or territory health department. The monitoring of compliance by these jurisdictions and the investigation of issues such as inappropriate use or prescribing by more than one doctor/practice to a consumer is all significantly dependent on the receipt of dispensing reports from pharmacies. Manual recording and non-real time reporting mechanisms slow this process down and are open to errors and omissions.

A move from manual to electronic recording and real-time reporting will improve the ability to efficiently monitor the prescribing and dispensing of Controlled Drugs to ensure appropriate access to these medicines. Real-time access to accurate dispensing information will improve the efficiency by which state and territory regulators, prescribers and pharmacists identify problems of forgery, abuse and doctor shopping and improve public health outcomes. Electronic recording will improve the accuracy and efficiency for pharmacists when recording transactions of Controlled Drugs.

The Fifth Community Pharmacy Agreement (Fifth Agreement) between the Australian Government and The Pharmacy Guild of Australia commenced on 1 July 2010. It is a five year agreement that recognises the important part that is played by community pharmacy in primary health care.

The Electronic Recording and Reporting of Controlled Drugs (ERRCD) initiative is one of the initiatives to be implemented under the Fifth Agreement. It aims to develop a nationally consistent system to collect and report data relating to the dispensing of Controlled Drugs which will complement and support the current regulatory controls required by states and territories.

Description

The Electronic Recording and Reporting of Controlled Drugs (ERRCD) initiative will see the development and implementation of software programs that will provide:

- a nationally consistent Controlled Drug Electronic Register;
- a nationally consistent electronic system to collect and report data relating to the dispensing of Controlled Drugs; and

- real-time access for prescribers and pharmacists to current information on dispensing events for Controlled Drugs.

On 12 February 2012, the Minister for Health, the Hon Tanya Plibersek MP, announced that a licensing agreement had been signed with the Tasmanian Department of Health and Human Services to use their existing Controlled Drugs monitoring system as the platform for the nationalised ERRCD system to be made available to all states and territories.

The ERRCD system will help enable prescribers, pharmacists and state and territory regulators across Australia to more effectively and efficiently monitor the use of these medicines.

What the system will do

The ERRCD system will collect information on all dispensing events related to Controlled Drugs consistent with state and territory legislation.

The system provides a source of data for prescribers, pharmacists and state and territory regulators about the dispensing of Controlled Drugs. This data will include information relating to the person who has been dispensed a Controlled Drug such as name, date of birth, as well as information on the medicine dispensed such as strength, form and date of dispensing.

In contrast to e-Health developments, the ERRCD system will not be an 'opt-in' system such as that proposed for the Personally Controlled Electronic Health Record.

How the system will work

The system will comprise of a number of components, some of which will be internet based. It will provide a web portal for both prescribers and pharmacists, and will integrate with pharmacy dispensing systems to capture information relating to the provision of Controlled Drugs.

The system will provide the capacity for state and territory regulators to access recorded information through a secure web interface allowing them to manage the system, and respond as required, to alerts that have been raised by the system.

During a clinical interaction, authorised prescribers and pharmacists may access data on a consumer via a secure web portal that may help to inform their clinical decision-making. The ability of prescribers and pharmacists to view the history of Controlled Drugs that have been dispensed to a consumer will be a key feature of the system.

¹ [www.health.gov.au/internet/ministers/publishing.nsf/Content/183A5624EC33E96FCA2579A400767F54/\\$File/TP014.pdf](http://www.health.gov.au/internet/ministers/publishing.nsf/Content/183A5624EC33E96FCA2579A400767F54/$File/TP014.pdf)



Protecting privacy

There are stringent laws in place regulating the handling of personal health data. The ERRCD system will comply with relevant standards for security of electronic and personal health data to a level compatible with PROTECTED data in accordance with the Australian Government Protective Security Policy Framework.

Implementation date

The electronic system to collect and report dispensing data relating to Controlled Drugs will be made available to State and Territory regulators from July 2012.

Given that regulations for Controlled Drugs are contained within State and Territory statutory rules, the implementation of this initiative will require amendments to these statutory rules in order to allow prescribers and dispensers to access information. The system will also need to integrate with existing state and territory information and communication technologies and processes. This will see some variation of the date between jurisdictions that the system becomes available for use.

Medicines included in this initiative

All medicines included in Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) which is given legal effect through state and territory legislation will be monitored by the ERRCD system. Schedule 8 of the SUSMP includes substances which should be available for use but require restriction in their manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence. In addition to Schedule 8 medicines, individual states and territories may use the ERRCD system to monitor other medicines that may be subject to jurisdictional regulatory arrangements.

All Controlled Drugs, whether they are dispensed as Pharmaceutical Benefits Scheme (PBS) or non-PBS (private) prescriptions, will be reported by the system.

Maintaining legitimate use of Controlled Drugs

The initiative is not intended to present a barrier to access for legitimate use of Controlled Drugs, such as consumers with severe chronic disabling pain or those receiving palliative care.

The ERRCD system will contain functions that allow authorised state and territory regulators to perform activities such as processing prescribing approvals for Controlled Drugs and managing Controlled Drug records. The system will allow regulators to determine breach conditions and set pre-defined criteria that will alert them to particular prescribing and dispensing activities that suggest forgery, abuse or doctor shopping. The breach alerts could be set to exclude dispensing events for particular consumer groups, such as palliative care patients.

Changes to prescribing and dispensing software

An interface between prescribing software and the ERRCD system is required so that prescribers can access the system from their prescribing software. Pharmacy dispensing software will be upgraded to facilitate integration with the ERRCD system.

Replacement of paper-based Controlled Drugs registers

Currently, it is a legislative requirement in all states and territories for all pharmacies along with other persons/facilities able to possess these substances, to record all transactions of Controlled Drugs. This register must also show the balance of Controlled Drugs on hand. This is in addition to the current arrangements of some states and territories where pharmacists are required to report the dispensing of a Controlled Drug by periodically sending prescription duplicates or records to their state or territory department of health.

This initiative will see the development of an Controlled Drug Electronic Register (CDER) that interfaces with existing pharmacy dispensing software. This function will assist pharmacists to efficiently meet their statutory obligations to maintain records of Controlled Drugs.

Although there are no national uniform regulations in place specifying the requirements for a CDER, the Commonwealth and The Pharmacy Guild of Australia will work closely with state and territory regulators to ensure that the CDER meets jurisdictional requirements and can be used in place of a paper-based Controlled Drugs register. This component of the initiative will be introduced separately to the reporting of dispensing events.

² www.ag.gov.au/Protectivesecuritypolicyframework/Pages/default.aspx

³ www.tga.gov.au/industry/scheduling-poisons-standard.htm