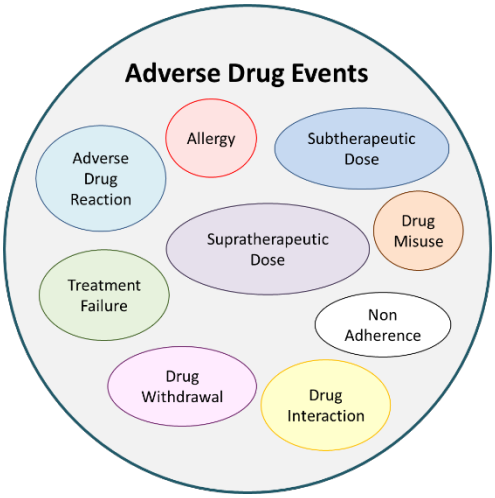
Adverse Drug Events vs Adverse Drug Reaction



An Adverse Drug Event (ADE) is "Harm caused by appropriate or inappropriate use of a drug whereas adverse drug reactions are a **subset** of these events, where harm is directly caused by a drug under appropriate use (i.e. at normal doses). Adverse drug events may include cases of provider error, non-adherence, or incorrect dosages. (Nebeker, Barach, & Samore, 2004).

Information recorded by acute care providers in PharmaNet will include a broad range of ADEs, including as a subset ADRs. As the PharmaNet system will flag these ADEs for review upon subsequent dispensations of the medication, it is important for community pharmacists to review the information contain in the comments of recorded ADR/ADEs to determine the most appropriate action.

The ActionADE research team have completed significant research into what details of an ADE should be recorded to accurately, but succinctly inform other care providers of the event. For more information on ActionADE you can visit their web page - https://actionade.org/

NOTE: ActionADE is a research project and thus there will be limited patients with ADE records. Pharmacists will still record ADRs as per the usual process in PharmaNet.

Display of ADE information in a Patient's PharmaNet Profile

Depending on the version of your WinRx software, ADE information will display differently. The most recent update to WinRx will present ADE information as a unified record "Adverse Event" in the patient profile. Previous versions of the software will present the information separated in the "condition" and "Reaction" sections; use *ADE to match the information together in this case.

The following ADE information will be recorded in the PharmaNet record:

CLINICAL CONDITIONS SECTION		
Data element	What it contains & allowed values	Comments
ADE Identifier	*ADE	Flags that this condition is associated with an ADE and its impact to therapy should be considered in the context of the ADE. The user must look for further details of the ADE in the 'Adverse Reaction' section. This can be done by matching the *ADE identifier.
Time Stamp	hh=hour (00 - 23) / mm=minutes (00 - 60)	Where a patient has multiple ADEs recorded, permits the matching of symptoms experienced in Clinical Conditions section to the correct ADE information recorded in the Adverse Reaction section.
Clinical Condition	Name of condition or symptom	Primary symptom/condition experienced as part of the ADE.
Comment Detail	Up to two further conditions/symptoms or lab value	Provides further details of symptoms experienced as part of the ADE, may also include a relevant lab value (eg. INR)
ADVERSE REACTION SECTION		

Data Element	What it contains	Comments
Drug Name and DIN	Drug name and DIN of the drug associated with the ADE.	This is often referred to as the culprit drug. PharmaNet will check any future dispenses against this DIN and flag as a prior ADR where a potential cross sensitivity exists. Users must review the ADE record to determine the appropriate action.
ADVERSE REACTION TAB – Comment Details		
1. ADE Identifier	*ADE	Flags that this record should be treated as an ADE versus ADR.
2. Time Stamp	hh=hour (00 - 23) / mm=minutes (00 - 60)	Where a patient has multiple ADE recorded, permits the matching of symptoms experienced in clinical conditions to the ADE information recorded in the ADR section
3. Adverse Drug Event Type	Adverse Drug Reaction Allergy Subtherapeutic dose Supratherapeutic dose Treatment failure Drug Withdrawal Drug Interaction Non-Adherence Drug Misuse	Defines the type of Adverse Drug Event. This informs users of the most appropriate clinical intervention. For example, a patient arrives in the ER experiencing seizures due to not taking their phenytoin. This would be documented as an ADE due to non-compliance, the expectation is that clinicians will encourage the patient to take their medication as prescribed to prevent a repeat of the ADE.
4. Certainty	Certain Likely Possible Unlikely Refuted	The level of certainty the acute care provider has that the culprit drug caused the associated symptoms/diagnosis. 'Refuted' indicates that the provider has determined that the drug did not cause this ADE. For example, allergy testing reveals that a rash subsequent to amoxicillin was likely attributed to use during a viral infection not a true allergy.
5. ADE Outcome	Death Permanent Disability Worsen Preexist Cond Fetal Defect Hospitalization Hospital Extended Emergency Visit Life Threatening	The outcome of the ADE event, it provides some insight to the severity of the ADE.
6. Dose with Units	free text	Included where applicable, eg. Subtherapeutic and Supratherapeutic dose.
7. Frequency	free text	
The information in the comment is entered in the above order with each data element separated by an underscore. Comment: *ADE_hhmm_Adverse Drug Event Type_Certainty_ADE Outcome_Dose_Frequency		

Example

CLINICAL CONDITION (ZPB1)	***ADE_1450_Deep vein thrombosis**
Clinical Condition Comment: INR=1	

ADVERSE REACTION (ZPB2)	**Warfarin - DIN 2240205**
Adverse Reaction Comment: ***ADE_1450**_Subtherapeutic Dose_Certain_Hospital extended_3mg_daily	

Recording your Clinical Decisions

The ActionADE research is dependent upon pharmacists recording in PharmaNet their clinical decisions based upon the ADE information presented to them.

The PharmaNet Drug Use Evaluation (DUE) will alert on an ADE as part of the claim process. The user must review the comment details of the ADR and match to the associated Clinical Condition, via *ADE_hhmm identifier, to assess how the ADE alert should be managed clinically. If your software does not permit you to review the details of the DIN on record which triggered the alert, users must review the patient profile to see the details of the ADE. As these are ADEs versus ADRs, **do not** assume the medication should be discontinued or replaced. In some cases, it is appropriate to ensure the patient takes their medication as in the case of an ADE due to non-adherence.

A) To record the clinical decision in response to ADE information subsequent to the DUE alert a pharmacist must manually reverse and resubmit any further claim with the appropriate reversal and rational codes
B) If an issue is noted prior to submission of a claim, the pharmacist can enter the rationale intervention code on the initial claim submission after making their clinical intervention.

PharmaNet Intervention Codes for Reversals due to ADE

Code	Description
RA	Due to ADE alert.
RD	Defer clinical decision.
RO	Override alert.

PharmaNet Intervention Codes to indicate a decision to proceed with the dispense despite the ADE information

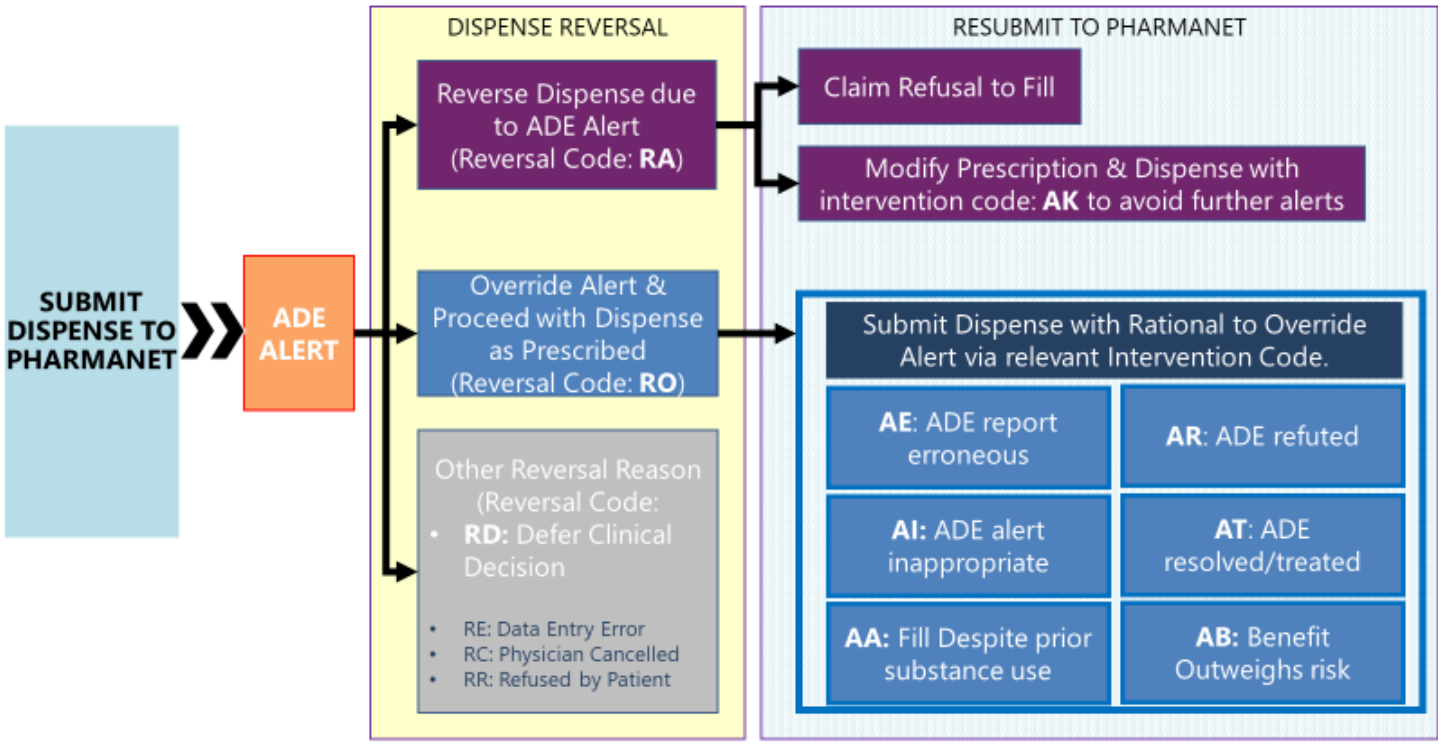
Code	Description
AA	Fill despite prior substance use.
AB	Benefit outweighs risk.
AE	ADE report erroneous.
AI	ADE alert inappropriate.
AR	ADE refuted.
AT	ADE resolved/treated.

PharmaNet Intervention Codes to indication a therapeutic change as a result of ADE information

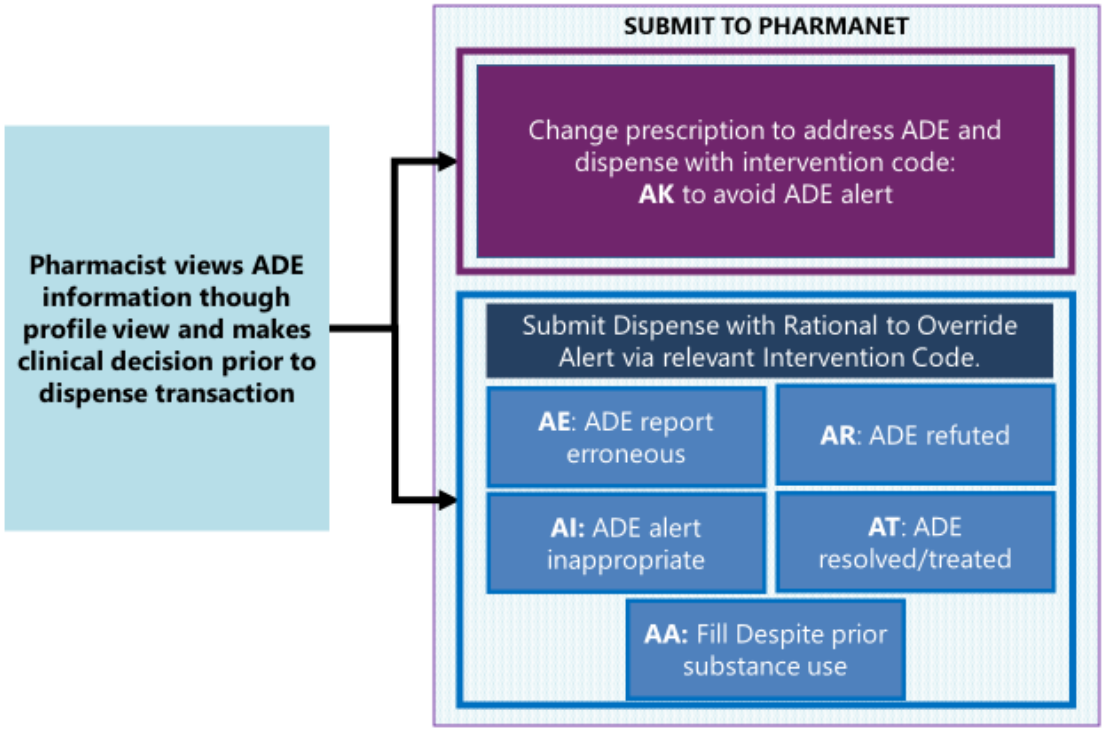
Code	Description
AK	ADE acknowledged and prescription changed.

Pharmacy Users – Workflow to record clinical decisions due to ADE information by pharmacists in PharmaNet.

A) Workflow if decision made at time of claim adjudication and display of PharmaNet DUE- prior ADE/ADR alert



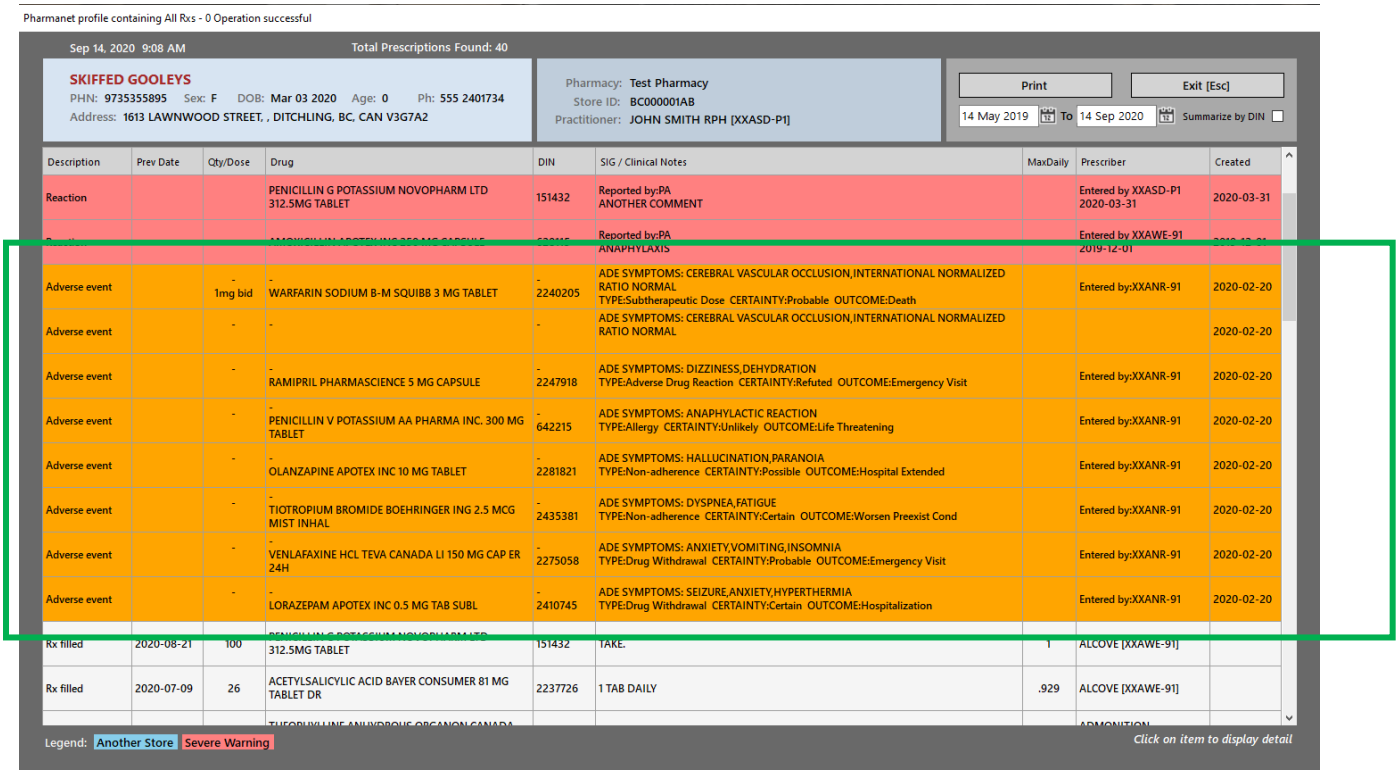
B) Workflow if decision made at time of profile view prior to submission of claim adjudication.



Display of ADE information in WinRx (Applied Robotics) – latest update

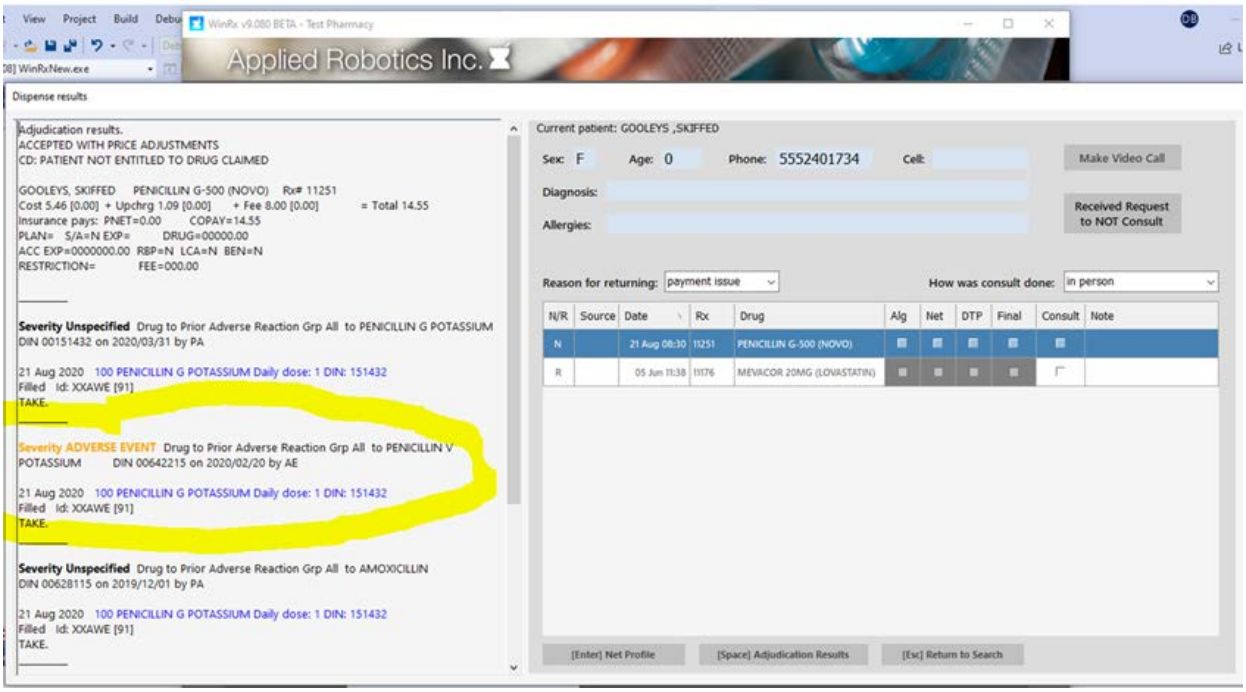
Patient Profile

A new group for "Adverse Event" has been added with headers in the notes reflecting the information inputted into PharmaNet by ActionADE



PharmaNet Drug Utilization Evaluation (DUE) Screen

Alerts for ADE are denoted as Adverse Event and coloured orange to differentiate from prior ADR.



Display of ADE information in WinRx (Applied Robotics) – previous software versions

Patient's PharmaNet Profile

The details of the ADE will be present in the patient profile screen. Note that this information is separated into the Condition section and the Reaction section. To match the information you must match the *ADE_hhmm together. In this case there are two ADEs. The black bracket matches *ADE_2310, and the blue bracket matches *ADE_1323. In most cases patients will not have more than one *ADE on their profile.

In the DUE screen, ADEs will flag as Prior ADRs. You must review the patient profile to assess the ADE details and determine the most appropriate clinical action.