# Notifications about controlled drugs: guidance for providers

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## 1. New notification on controlled drugs

From 1 April 2015, a new notification is being introduced to alert the Care Inspectorate to any adverse events and concerns involving schedule 2, 3, 4, and 5 controlled drugs used in care settings. This follows changes to The Controlled Drugs (Supervision of Management and Use) Regulations 2013.

A copy of the Regulations can be found here:
http://www.legislation.gov.uk/uksi/2013/373/contents/made

Providers should notify the Care Inspectorate of all adverse events and concerns involving a controlled drug when they occur, and while the service user is receiving care in the care service. This includes cases where a person uses a 24-hour service, but was not present in that service at the time that the incident was identified, for example they were in hospital or on an outing. In other services, the notification should be made if the incident occurs or was identified when the service was being provided.

Notifications should be made through the Care Inspectorate's eForms system as at present. The eForm contains guidance on the type of notifiable events.

The purpose of the notification is to provide a summary of the event and subsequent action taken.

It should include the following information:

- a summary of event, including the date, time and location (as appropriate), and the name of the Controlled Drug and route of administration
- impact or likely impact on the health and well-being of the service user
- immediate action taken by the care provider
- the outcome of any investigation and any subsequent action (this may be submitted as an update notification)
- clarify if external agencies have been notified, for example the police or the local authority.

The information provided within the notification may be shared with the Controlled Drug Local Intelligence Networks.

## 2. What controlled drugs does this apply to?

This guidance applies to Schedule 2, 3, 4 and 5 controlled drugs. It does not apply to Schedule 1 Drugs (CD Lic) which are not recognised as having any medicinal use or to illicit drugs.

| **Examples of controlled drugs include:** | |
|---|---|
| Schedule 2 | Morphine, Pethidine, Fentanyl, Diamorphine |
| Schedule 3 | Temazepam, Midazolam, Buprenorphine, Tramadol |
| Schedule 4 | Benzodiazepines (Diazepam) and anabolic steroids |
| Schedule 5 | Dihydrocodeine, Codeine Linctus, Co-codamol |

## 3. Notifications guidance

This guidance covers all services

**Information Covered**

Notifications must be made for the following types of events involving schedule 2-5 controlled drugs:

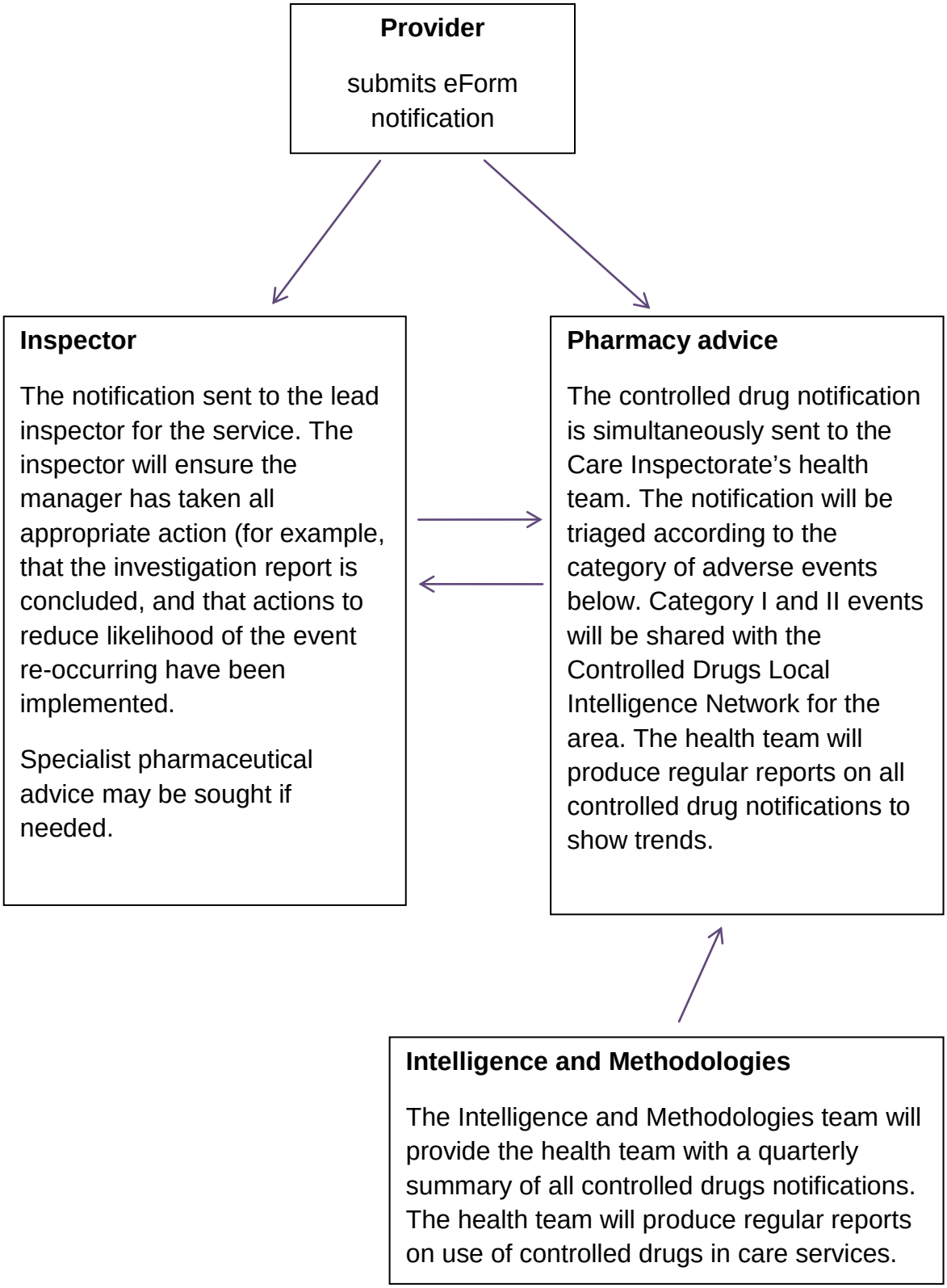
- Prescribing or dispensing error by e.g. pharmacy or doctor/dentist
- Prescribed medication not available to be administered
- Person given wrong dose of medication
- Person given wrong medication
- Medication not recorded as given and no recorded explanation or justification
- Medication incident/error resulting in injury
- Medication incident/error referred to the police
- Medication incident/error referred to the Procurator Fiscal
- Medication incident/error requiring input or advice from healthcare professional
- Medication incident/error resulting in hospital admission
- Medication incident/error considered as an adult or child protection matter.
- Medication incident/error: 'near miss' that could have led to injury of harm
- Medication missing or stolen
- Medication or controlled drug records falsified
- Staff referred to professional registration body re: medicines management
- Staff left during or before investigation re: missing or stolen medication
- Staff left during or before investigation re: poor practice in management and administration of medication

**Timescale**

Services should report the incident within 24 hours, with any follow up notification (e.g. outcome of investigation) reported as soon as appropriate.

## 4. What will the Care Inspectorate do with the notifications?

This flowchart shows how the Care Inspectorate will handle the information received from the notification.



## 5. Categories of adverse events

When considering notifications, the Care Inspectorate will classify adverse events in three categories:

**Category I**
Events that may have contributed to or resulted in permanent harm (for example unexpected death, intervention required to sustain life) or known theft of controlled drugs requiring police intervention.

**Category II**
Events that may have contributed to or resulted in temporary harm, or where intervention or monitoring required was required, or suspected drug discrepancy.

**Category III**
Events that had the potential to cause harm but no harm occurred (for example near miss or low impact events).

Details of Category I and II adverse events may be shared with the NHS Board Accountable Officer for the part of the country where the incident took place. This is likely to be where the incident involved a prescribing or dispensing error.

Anonymised information about all incidents will be shared with relevant members of the Local Intelligence Network set up by the NHS Board Accountable Officer.

More information about the Controlled Drugs NHS Board Accountable Officers and Local Intelligence Networks and controlled drugs in general can be found in "A guide to good practice in the management of controlled drugs in primary care – Scotland: version 2.0" at http://www.knowledge.scot.nhs.uk/media/CLT/ResourceUploads/4055959/Primary_Care_Guide_Scotland_v.2.0_171114.pdf

## 6. How will the inspector use the information from the notification?

From 1 April 2015, the Care Inspectorate is changing the way we respond to information provided in notifications and whether or not we re-grade them.

Inspectors can re-grade following notifications of incidents in care services, but if a notification is serious enough to warrant re-evaluation, serious consideration must be given to bringing forward the next inspection. This decision should be made in light of all the intelligence known about the service and the risk assessment of it.

However, if re-grading is considered, we will consider re-grading based on the actions the provider takes and not the subject matter of the notification, or the simple fact that a notification has been made.

We will not re-grade a service simply because they have followed the proper guidance and notified us of an issue.

**Headquarters**
Care Inspectorate
Compass House
11 Riverside Drive
Dundee
DD1 4NY

**web: www.careinspectorate.com**
**email: enquiries@careinspectorate.com**
**telephone: 0845 600 9527**

**@careinspect**

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