NHS England, East of England, Controlled Drugs Team

NHS England East of England

Controlled Drugs Newsletter

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This newsletter contains information to support safe use and handling of controlled drugs

NHS England, East of England CD team

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Legislation: healthcare professionals can be defined as 'relevant individuals'

Controlled Drug regulations relating to Primary Care (including in general practice, community pharmacy, and dental practice) require a CDAO to ensure there are arrangements for monitoring and assessing the performance of a 'relevant individual' in connection with the management and use of CDs and determining whether incidents or concerns require investigation.

So, who is a relevant individual?

Healthcare professionals can be considered 'relevant individual[s]' as defined within the Health Act 2006 part 3, chapter 1:

"relevant individual" means an individual who, whether as—

(i) a health care professional, or

(ii) an employee who is not a health care professional, or

(iii) otherwise,

is engaged in any activity carried on by a body or person within subsection (7)(b) or (c) that involves, or may involve, the management or use of controlled drugs

Note, this includes providing healthcare services to private patients.

The CDAO for primary care services is the regional NHS England CDAO. The arrangement in place for reporting incidents and concerns is to use CD reporting.

When reporting an incident please remember to include names of 'relevant individuals' who were involved in the incident, and the names of all relevant individuals who had access to missing CDs if an incident involves missing CDs.

Note – The Controlled Drugs (Supervision of Management and Use) Regulations 2013 provide more specific details in relation to the meaning of "relevant persons"

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Useful Websites

CD Reporting
www.cdreporting.co.uk

Home Office
https://www.gov.uk/government/organisations/home-office

Department of Health
https://www.gov.uk/government/organisations/department-of-health

General Pharmaceutical Council
www.pharmacyregulation.org

Care Quality Commission
http://www.cqc.org.uk/

NHS Prescription Services CD section
https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/prescribing-and-dispensing/safer-management

Community Pharmacy England
Dispensing & Supply - Community Pharmacy England (cpe.org.uk)

Regulatory requirements for healthcare professionals collecting schedule 2 CDs

We would like to remind community pharmacies of the regulatory requirements when healthcare professionals collect schedule 2 CDs. The following is extracted from The Misuse of Drugs Regulations 2001 section 16, part 6:

Reg 16 - Provisions as to supply on prescription

(6) A person who is asked to supply on prescription a controlled drug specified in Schedule 2 must first ascertain whether the person collecting the drug is the patient, the patient's representative or a healthcare professional acting in his professional capacity on behalf of the patient; and—

(a) where that person is the patient or the patient's representative, he may—

(i) request evidence of that person's identity; and

(ii) refuse to supply the drug if he is not satisfied as to the identity of that person;

(b) where that person is a healthcare professional acting in his professional capacity on behalf of the patient, he—

(i) must obtain that person's name and address;

(ii) must, unless he is acquainted with that person, request evidence of that person's identity; but

(iii) may supply the drug even if he is not satisfied as to the identity of that person.

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CD register reminders – community pharmacy & dispensing GPs

In order to comply with The Misuse of Drugs Regulations 2001 for CD registers:

- there should only be one active CD register (**NB** for primary care, expired stock must be kept in the running total of the register until denatured, **NOT** entered into a separate register)
- a separate part of the register must be used for each class of drug. Separate sections should be used in respect of each strength or form of that drug and the head of each such page should specify the class of the drug, its strength and form. Only one register should be kept at one time in respect of each class of drugs
- every entry should be made on the day on which the drug is obtained/supplied: if that is not reasonably practicable, the entry should be made on the following day
- entries should be made in chronological sequence
- no cancellations, obliterations or alterations of any entry should be made and any corrections should consist of a marginal note or footnote which specifies the date of the correction
- every entry and correction should be made in ink or should be in computerised form (for electronic registers) in which every such entry is attributable and capable of being audited and which is in accordance with best practice guidance
- every register in which entries are currently being made must be kept at the premises to which it relates and, where the register is in computerised form, be accessible from those premises

Electronic registers – Royal Pharmaceutical Society (RPS) guidance confirms that CD registers may only be held in a computerised form if safeguards are incorporated into the software to ensure all of the following:

- The author of each entry is identifiable
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes

SOPs – Premises must have SOPs relating to the management and use of controlled drugs including record keeping and maintaining CD registers.

Balance checks - It is considered good practice to perform balance checks when dispensing CDs and ensure checks of all the registers and stock are performed at least quarterly.

Patient returns registers - Patient returned CDs should be entered into the patient returns register within 24 hours to ensure a clear audit trail and then stored appropriately in the CD cupboard, segregated from stock until denatured to reduce the risk of a dispensing error.

Archiving registers - Any full or retired registers must remain on the premises for at least two years after the date of the last entry.

For reference: Dispensing Controlled Drugs - Community Pharmacy England (cpe.org.uk)
GP mythbuster 28: Management of controlled drugs - Care Quality Commission (cqc.org.uk)

Used fentanyl patches – safe disposal

Transdermal delivery systems work via a concentration gradient. When a patch is applied the drug starts to move down the gradient into the skin, through the skin layers and into the bloodstream. To maintain the concentration gradient for the duration of the patch application the patch will, at the point it is fully 'used', still contain a significant amount of the drug and must therefore be disposed of properly.

For example, fentanyl 100mcg/hr patches contain 10mg (10,000mcg) of fentanyl. Theoretically 100mcg/hour for 72 hours will use 7200mcg leaving 2.8mg remaining in the patch.

It is generally thought that 2mg of fentanyl is a lethal dose for most people, though this can vary widely depending on combination with other drugs and patient related pharmacokinetic factors.

Used fentanyl patches are particulary dangerous to children as highlighted by: Transdermal fentanyl "patches": reminder of potential for life-threatening harm from accidental exposure, particularly in children - GOV.UK (www.gov.uk)

"Children are at risk as they may touch, suck, chew, or swallow a patch that has not been disposed of properly. Also, children have a lower threshold for fentanyl overdose than adults."

There is a high risk of diversion and misuse of fentanyl patches - there are two types of patch delivery system used for fentanyl; the reservior system (misused by the fentanyl being removed by using a needle or breaking the reservior) or a matrix system (misused by the fentanyl being removed by heating or boiling the patch in water).

The Medicines and Healthcare products Regulatory Agency (MHRA) issued guidance for patients in October 2018: Fentanyl patches: How to use and dispose of them safely Fent-patient-sheet-FINAL.pdf (publishing.service.gov.uk) which states 'dispose of old patches as instructed by your pharmacist'.

If a patient seeks to return any 'used' fentanyl patches to your community pharmacy please consider the information above and treat them as any other patient returned schedule 2 medicine, i.e. record in a patient returns book and keep securely in a CD cabinet until ready to be destroyed. The patches should be denatured using a CD denaturing (DOOP) kit prior to putting in a medicines destruction container.

When dispensing patches containing controlled drugs please advise patients, particularly those using fentanyl patches, how to store and dispose of used patches safely.

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Paramedic prescriber update

As of 31 December 2023, under The Misuse of Drugs Regulations 2001 a paramedic independent prescriber may prescribe any of the following controlled drugs for the treatment of organic disease or injury provided the controlled drug is prescribed to be administered by the specified method —

(a) Morphine sulphate by oral administration or by injection;

(b) Diazepam by oral administration or by injection;

(c) Midazolam by oromucosal administration or by injection;

(d) Lorazepam by injection;

(e) Codeine phosphate by oral administration.

Useful links

Specialist Pharmacy Service (SPS)

- Using benzodiazepines during breastfeeding – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Advisory Council on the Misuse of Drugs (ACMD)

- ACMD work programme 2024 (accessible) - GOV.UK (www.gov.uk)
- Uncontrolled novel benzodiazepines: 2024 update - GOV.UK (www.gov.uk)
- ACMD advice on 2-benzyl benzimidazole and piperidine benzimidazolone opioids - GOV.UK (www.gov.uk)

How to contact the East of England Controlled Drugs Team

East of England CD team primary contact is **england.ea-cdao@nhs.net**

This inbox is continuously monitored during normal working hours. If you need to speak to someone urgently, please email us requesting a call back with your phone number included.

To report a CD incident or concern or request an Authorised Witness please go to:
www.cdreporting.co.uk