

Medicines Optimisation Team STANDARD OPERATING PROCEDURE- WITNESSING THE DISPOSAL OF STOCK EXPIRED CONTROLLED DRUGS

Standard Operating Procedure Statement

This document sets out how the Medicines Optimisation Teams (MOT) in NHS Suffolk and North East Essex Integrated Care Board (SNEE-ICB) manage the process for controlled drug destruction within GP practices/ providers.

Information provided in this document is as accurate and up to date as possible, however the legal and regulatory framework governing Controlled Drugs (CDs) is continuing to change significantly and readers are advised to cross check the information with other recognised sources of information. It is the responsibility of staff to ensure they are following the Standard Operating Procedure (SOP) and by doing so, quality of service will be maintained, and risk of error will be reduced.

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Introduction

Controlled Drug Accountable Officer (CDAO) Contact details

- CD accountable officer england.ea-cdao@nhs.net
- To report an incident or request a CD witness <http://www.cdreporting.co.uk>
- General Enquiries Tel: 0121 611 0816

1. **Purpose** - to ensure legal, secure, safe, and appropriate destruction of controlled drugs within the specification and scope of this procedure
2. **Risk** - Failure to follow the SOP may lead to:
 - An unsafe build-up of date expired CDs
 - CDs being disposed of in an inappropriate or illegal manner
 - Incorrect and incomplete records and audit trail for CDs
 - Failure to address poor practice
 - Failure to identify diversion of CDs
3. **Scope** - this SOP refers to **expired stock** kept within a GP practice/ provider that does not have an accountable officer and covers:
 - Who is able to destroy CDs
 - Who is able to witness the destruction of CDs
 - A process that will be used to render the CDs irretrievable
 - How to report errors
4. **Responsibilities for Legislation and Good Practice**
 - 4.1 The witness must be authorised by the local Area Team CDAO to witness the destruction of controlled drugs
 - 4.2 The authorised witness (AW) is **not** authorised to witness the destruction of **Schedule 1** controlled drugs. If the GP practice has schedule 1 CDs, advice must be sought from the CDAO
 - 4.3 **Schedule 2** CDs must have an authorised witness to observe the destruction under the Misuse of Drugs Regulations 2001 (excluding patient returns).
 - 4.4 Destruction of **Schedule 3, 4 and 5 CDs does not require** the presence of an authorised witness.

4.5 [Care Quality Commission \(CQC\) guidance](#) indicates that for **Schedule 3** CDs, it is good practice to have another member of staff witness the denaturing.

4.6 CDs which are destroyed must have the following details recorded in RED pen:

- ☐ date of destruction
- ☐ drug quantity destroyed
- ☐ drug name
- ☐ form
- ☐ strength
- ☐ the words 'destroyed - expired stock'
- ☐ printed name and signature of the persons witnessing and destroying the drugs including,
 - General Pharmaceutical Council (GPhC) number of registered AW (unless an electronic register is being used in which case all details are recorded electronically)
 - Authority under whom they are acting – SNEE ICB (on behalf of NHSE)
- ☐ Updated running balance

4.7 Any date expired stock should be stored securely in the CD cabinet clearly labelled as out of date and segregated from non-expired stock to avoid potential dispensing error or re-use

4.8 The expired stock must be included in the running balance of the relevant register until it has been destroyed in the presence of the AW.

4.9 A record of all CDs destroyed should be scanned and emailed to the Area Team CDAO and kept in the Medicines Optimisation Team shared drive for future reference.

4.10 **Doctors Bags** - Any controlled drugs used in doctors' bags must have been signed out of the CD register and into the register for relevant doctors' bag. Once expired, they must be signed back in to the main CD register and added to the running total for destruction.

5. Training & Reauthorisation

5.1 Witnessing of destruction should only be assigned to those members of the Medicines Optimisation team who are authorised by the CD Accountable Officer. (A list is attached in appendix B)

5.2 **Only the CD Accountable Officer can authorise witnesses**

5.3 AWs must be Registered Pharmacists or Registered Pharmacy Technicians

5.4 AWs must have had a Disclosure and Barring Service certificate

5.5 AWs must receive appropriate training on CD destruction based on adherence to this SOP and any training materials produced by NHSE

- 5.6 The AW must have completed training and be signed off by the Controlled Drugs Accountable Officer before undertaking witnessing the destruction of any controlled drugs
- 5.7 All AWs must adhere to this SOP
- 5.8 Training should be recorded in the member AWs training records
- 5.9 Training must be revalidated by NHSE every two years. Re-validation forms are to be requested from the local team CDAO before the certification expiry. These must be completed by the AW and their line manager.
- 5.10 A peer discussion is required with another AW in order to complete these forms, and a minimum of two destructions must have been undertaken in the previous year. Forms are to be sent back to the local team CDAO.
- 5.11 Authorised witnesses should only witness destruction in those contracted services where they do not currently provide medicines management support.
- 5.12 If the AW has previously provided regular medicines management support to a practice, then they must have one year post regularly working at the premises before being able to be an AW for the practice

6. Preparation

- 6.1 When a request is received for a CD destruction visit, ensure the practice / provider has an SOP in place covering the disposal of CDs. The practice/ provider must request the destruction using <https://www.cdreporting.co.uk/>
- 6.2 Practices should have sufficient DOOP® (Destruction of Out-of-date Products) containers available for the quantity of drugs to be destroyed. These can be obtained from pharmaceutical wholesalers. Where possible, the CD denaturing kits should state on the instructions that tablets do not need to be crushed.
- 6.3 Advise the practice/ provider to register a T28 exemption with the Environment Agency to allow them to denature the CDs, if they haven't already done so. The AW must ensure the practice has a valid T28 exemption certificate before arranging a visit. This can be done by checking online using the link, <https://environment.data.gov.uk/public-register/view/search-waste-exemptions> or by asking the practice to confirm this by ticking the appropriate box on the 'Record of CD destruction form' (Appendix A) and recording the licence number.
 - *Destruction visits should not be arranged without a valid T28 certificate in place.*
- 6.4 Send the 'CD record of destruction list' (appendix A) and a copy of this SOP to the practice/ provider prior to attendance and ask the practice to complete the details and return the form to you prior to the visit. The AW must check that the medications listed on appendix A do require the presence of the authorised witness (check that the medications are not all schedule 3 or patient returns for example). Patient returns do

not need an AW to witness their destruction and so the AW can decline to witness these.

6.5 Inform the practice/ provider they must ensure they have enough staff available to carry out the destruction as **you are only there as a witness** and to advise on best practice. The member of staff carrying out the destruction must have protected time to safely and efficiently carry this out without interruptions.

6.6 Ask the practice/ provider to confirm they have everything in place before making the appointment:

- A recent stock balance check has been undertaken (no more than 7 days before the visit) and there are no discrepancies with the drugs they have asked you to destroy. Any discrepancies are to be reported in line with their SOP
- Valid T28 certificate.
- Sufficient Denaturing kit(s) which state that tablets do not need to be crushed • Practice SOP
- Necessary equipment (Needles, syringe, gloves, sharps bin, breakers, counting tray, container to collate de-blistered tab/caps)
- Sufficient space to carry out the destruction

6.7 If the practice/ provider uses an electronic CD register, allow two weeks before booking the visit to gain access to the system. The practice manager or relevant member of staff from the practice/ provider must inform the Authorised Witness which electronic register is being used and how to gain access. The “Authority to Witness the Destruction of Controlled Drugs” paperwork may be required by the manufacturer of the electronic register before access can be granted via a password/ PIN.

6.8 Book a suitable time to witness the destruction when the ‘CD record of destruction list’ (appendix A) has been completed and returned. Make sure the following are aware of the visit:

- Practice manager for the surgery
- Dispensary manager (if applicable)
- Medicines Optimisation Team line manager

6.9 When attending the destruction, make sure you take identification (wear your NHS badge) and know your GPhC registration number to record in the controlled drugs register where necessary as a record of your authorisation as a witness. The AW must also take a copy of their AW authorisation form with them. A red pen is also required when writing in the register.

7. Process

- 7.1 Arrive at the agreed time and ensure that the named person from the contracted service is available for the destruction. If not present, and an alternative appropriately qualified individual is not available then the appointment will need to be re-scheduled.
- 7.2 Make sure all equipment and documentation are available and useable. (Registers, Drugs, DOOP containers, sharps bin, gloves etc.)
- 7.3 Familiarise yourself with the CD register before any destruction is undertaken.
- 7.4 Check the register is completed appropriately and that a running balance is maintained.

7.5 It is not legal practice to transfer out of date CDs in to a second book or patient returns register for the purpose of destruction. If this has happened ONLY proceed if you are confident that the stock has been fully accounted for in the CD register. Ensure further entries are made in the CD register.

7.6 Controlled Drugs must be denatured before disposal. The process used by the practice/ provider staff should be in accordance with their own Standard Operating Procedure. Although the practice/ provider is responsible for the process they use, they are expected to meet Home Office/ RPS guidance. The AW should offer guidance including, if necessary, rescheduling the visit until the process can be carried out safely and in line with legislation.

7.7 Best practice guidance:

Before opening the DOOP kit, read the instructions carefully as not all DOOP kits require the same methods

- Protective gloves must be worn
- The CDs for destruction should be added to the kit in the following order:
 - tablets ○ capsules ○ lozenges
 - powder containing injections ○ transdermal patches
 - Small volume liquids e.g. injection ampoules ○ Large volume liquids e.g. oral liquids

7.8 Processing products before adding to kit:

Tablets and capsules must be removed from all packaging before being placed in the denaturing kit. For safety reasons, tablets should not be crushed, and capsules should not be opened due to risk of inhaled powder.

7.9 Lozenges should be removed from the stick and added to the denaturing kit.

7.10 Injection ampoules/vials must be opened and the contents and glass added to the kit separately– protect hands when breaking glass. Liquids in ampoules may need to be removed using a needle and syringe due to the vacuum preventing the pouring out of the liquid. Powders within the ampoules should have water added to them using a

syringe and then this can be withdrawn using a needle and syringe. Used needles and syringes are to be added to the denaturing kit.

- 7.11 Transdermal patches – remove patches from the sealed pouch and remove the backing. Fold the patch in half so that the adhesive surfaces stick together. Place directly into the DOOP kit and include the backing.
- 7.12 Liquids should be measured and emptied from the container into the DOOP kit and the container rinsed with a small volume of water which is also then added to the kit.
- 7.13 **The CD register** must be completed at the same time as Appendix A, after each individual drug has been added to the DOOP kit. Use an entire line on the specific page of the CD register. The following information must be written into the register in **RED** pen:
 - ☐ date of destruction
 - ☐ drug quantity destroyed
 - ☐ drug name
 - ☐ form
 - ☐ strength
 - ☐ the words 'destroyed - expired stock'
 - ☐ printed name and signature of the persons witnessing and destroying the drugs including,
 - General Pharmaceutical Council (GPhC) number of registered AW (unless an electronic register is being used in which case all details are recorded electronically)
 - Authority under whom they are acting – SNEE ICB (on behalf of NHSE)
 - ☐ Updated running balance
- 7.14 If an electronic register is being used, all information is added electronically. There are various manufacturers of electronic registers and so the procedure for entering the destruction should be confirmed when applying for access to the register.
- 7.15 Once all products have been added to the kit, water must be added as necessary in accordance with the manufacturer's instructions.
- 7.16 The inactivation process may take up to 24/48 hours depending on the kit used and the kit must be stored inside the CD cupboard for this period (it is good practice to secure the lid with tape). Write the date destroyed onto the DOOP kit. After the specified time, the CDs can be considered irretrievable and so the DOOP kit can be placed into the pharmaceutical waste
- 7.17 The authorised witness should complete the audit form on the reverse of the 'CD destruction record list' (Appendix A) to capture basic information regarding the management of CDs on the premises. If any changes in practice are required following the AW visit, the AW must communicate these to the practice manager and follow this up in an agreed period of time. This should be recorded on the reverse of Appendix A.
- 7.18 The completed CD destruction record list (Appendix A) should be emailed to the Area Team CD Accountable Officer england.ea-cdao@nhs.net and a copy kept for your

own team records on the shared drive. It is also good practice for the practice/ provider to take a copy of the forms whilst the AW is on site so that they also have a record. Alternatively, they can be copied into the email to the CDAO team.

8. Reporting Errors

- 8.1 Any discrepancies identified during the process (for example the quantity in hand does not match the quantity in the register) should be reported to the practice/provider manager and investigated and accounted for before the stock is denatured. The root cause of the error must be established. Any entry made into the register must explain the error. Previous entries must not be altered.
- 8.2 The practice/ provider staff are responsible for the investigation, but the AW may seek advice from Senior members of the Medicines Optimisation Team and/ or NHSE. If it is necessary to contact NHSE, the Practice or provider Manager should be advised and made aware that NHSE may contact them regarding the investigation.
- 8.3 The presence of discrepancies does not necessarily prevent the destruction of CDs from taking place. The AW should consider the risks (if any) of not destroying the CDs during the visit.
- 8.4 If the discrepancy cannot be resolved, the practice/ provider manager should record the incident and report it to the NHSE CD Accountable officer in line with their SOP.
<https://www.cdreporting.co.uk/nhs/account/signin>
- 8.5 Authorised witnesses should not undertake an NHSE investigation themselves.
- 8.6 NHSE must liaise directly with the practice/ provider manager in the case of any identified errors that need to be resolved.

9. Monitoring and Auditing

Monitoring the adherence of this SOP will be the responsibility of Medicines Optimisation Team in conjunction with NHSE local area team



Record of controlled
drug destruction visit

References

Care Quality Commission

<https://www.cqc.org.uk/guidance-providers/gps/gp-mythbuster-28-management-controlleddrugs>

Gov.UK information and list of controlled drugs

<https://www.gov.uk/search?q=Controlled+drugs&tab=government-results>

Misuse of Drugs Act (MDA) 1971 legislation

<http://www.legislation.gov.uk/ukpga/1971/38>

Misuse of Drugs Regulations 2001

<https://www.legislation.gov.uk/uksi/2001/3998/contents/made>

Misuse of Drugs (Safe Custody) Regulations 1973

<http://www.legislation.gov.uk/uksi/1973/798/contents/made>

NICE Guideline NG46- Controlled Drugs: Safe use and management

<http://nice.org.uk/guidance/ng46>

Royal Pharmaceutical society

<https://www.pharmacyregulation.org/standards>

The Controlled Drugs (Supervision of Management and Use) Regulations 2013

<http://www.legislation.gov.uk/uksi/2013/373/contents/made>

Controlled drugs and drug dependence regulations and classification

<https://bnf.nice.org.uk/medicines-guidance/controlled-drugs-and-drug-dependence/>

APPENDIX A - CD DESTRUCTION FORM

NHS England and NHS Improvement, East of England Record of Controlled Drug Destruction Visit

Provider/Organisation name:	
Address:	
Telephone number:	
Email address:	
Contact name:	
Date & time of visit:	

Controlled Drug (CD) pre- destruction checklist

Please tick to confirm

1. A suitably trained member of staff to carry out the destruction ☐

2. A current [T28 exemption certificate](#). Record certificate number..... ☐
3. DOOP kit(s) of a suitable size ☐
4. Safety equipment as required e.g. gloves, mask, appropriate PPE, syringe with needle, scissors. ☐
5. Your SOP for destroying CDs ☐
6. Recent balance check recorded ☐

Expired stock must be stored securely in the CD cabinet. It should be clearly labelled as out of date and segregated to prevent dispensing errors. The stock must continue to be included in the running balance in the CD register until it has been destroyed.

Patient returns – Do not need to be destroyed by an authorised witness

ICB/Alliance AWs: Please return your completed form to the CDAO via england.ea-cdao@nhs.net

Record of Drugs destroyed

	Drug	Expiry Date	Strength	Form	Quantity	Sign on destruction
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						

12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						

Details below to be completed by Authorised Witness during destruction visit			
Name and role of person destroying drugs			
Authorised witness			
	Response	Advice provided by AW	For Action by:

Where is the CD key kept? On the authorised person?			
Frequency of balance checks	Usual frequency: Date of last balance check:		
Have there been any CD related incidents or concerns within the past 6 months. If yes, please give a brief summary.			
Is the overage of liquids adequately recorded			
Is expired stock kept in the running balance until destroyed			
How frequently are patient returned drugs destroyed			
Are similar drugs/ drug strengths			
appropriately separated			

Additional Notes/Actions (other CD issues observed or discussed during the visit; photos taken)

Follow up (e.g. What advice did you give and what do you/they need to do to carry out the advice. Timeline for recommendations to be actioned/ implemented?)

Signed by person doing destruction:

Signed by Authorised Witness:

Date:

Once completed, please return this form to
england.ea-cdao@nhs.net

APPENDIX B - DECLARATION

All authorised witnesses must sign the declaration below to confirm that they have read, understood, and will abide by this SOP.

Name of authorised witness	Designation	Signature	Date