Standard Operating Procedures for Controlled Drugs record keeping

(Page 1 of 12)

Objectives

These SOPs are designed to ensure that CD (controlled drugs) regulations and best practice guidance are followed when keeping records of activities relating to their receipt, supply and destruction:

- 1. <u>Creating a new schedule 2 CD register</u>
- 2. Recording receipt of schedule 2 CDs
- 3. Recording supply of schedule 2 CDs
- 4. Recording a stock balance check
- 5. Recording a destruction of schedule 2 CDs in the presence of an authorised witness
- 6. Recording entries in the patient-returned CD register
- 7. Making an amendment to a previous record
- 8. Archiving a CD register
- 9. Merging patients
- 10. Merging prescribers

Scope

These SOPs relate solely to the use of the PharmCD web application (https://pharmcd.co.uk) for fulfilling the requirements of the pharmacy or dispensary for maintaining records of CDs processed. The SOPs does not cover how to fulfill these obligations by any other method or software.

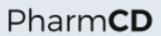
Responsibility

Only those members of staff who have been considered competent and listed in the declaration of competence can carry out these procedures.

Review

The SOPs will be reviewed every two years by the Responsible Person (RP) to reflect any changes to legislation or best practice guidance affecting record keeping of CDs.





Standard Operating Procedures for Controlled Drugs record keeping (Page 2 of 12)

Associated risks

PharmCD is a web-based application, and so the organisation should ensure that internet access is consistently available to devices which are to be used to access PharmCD.



Standard Operating Procedures for Controlled Drugs record keeping (Page 3 of 12)

Creating a new schedule 2 CD register

Records for the receipt or supply of schedule 2 CDs must be maintained within the relevant register for that medication. A register for a specific medication only needs to be created once within PharmCD. Registers are either created when the pharmacy or dispensary first receives a supply of that medication, or when the management of records for an existing CD register (e.g. paper) are being transferred to PharmCD for future record keeping.

- Access/login to PharmCD access the PharmCD web app from the device web browser, and login using the premises account details (if not already logged in). Click the Registers dropdown button on the PharmCD app, and then click the ADD NEW REGISTER button.
- 2. On the "Migrate Registers" popup, click the "Search" textbox and type the name of the medication which you're wanting to create a register for. Wait for the suggestions to appear below the textbox, and click on the correct medication.
- 3. Click on the "Opening Balance" textbox and type in the opening balance quantity. For a new register, this should always be zero; for a register which is being transferred to PharmCD, then the opening balance will be the current balance after all entries of supplies and receipts have been recorded already.
- 4. Click the ADD REGISTER button and the new register will be successfully created.

Recording receipt of schedule 2 CDs

Schedule 2 controlled drugs should have an entry made in the relevant CD register when a supply is received into the pharmacy or dispensary. Supplies are typically from pharmaceutical wholesalers, but may also be from another pharmacy or dispensary, or from a failed medication delivery to a patient which then has to be returned to safe custody within the CD cupboard.

- Access/login to PharmCD access the PharmCD web app from the device web browser, and login using the premises account details (if not already logged in). Click the BOOK IN button to launch the "Quick Book In Stock" popup window.
- 2. On the "Quick Book In Stock" popup, amend the "Entry Date" to the date of receiving the medication, select the medication supplier from the "Select



Standard Operating Procedures for Controlled Drugs record keeping

(Page 4 of 12)

Supplier" dropdown list, and enter the invoice number (if applicable) in the "Invoice No." textbox. Click the "Search Product" textbox and begin typing the name of the medication; wait for the suggestions to appear below the textbox, and then click on the correct medication register. Enter the quantity received into the "Quantity" textbox and, if you've verified the new balance of that medication within the CD cupboard, then tick the "Balance Checked?" checkbox. Finally, click the BOOK IN button.

- a. If the supplier that you've received medication from isn't in the dropdown list, then press the <u>NEW SUPPLIER</u> button to launch the "Add Supplier" popup. Enter the supplier name and address, and then press the <u>ADD SUPPLIER</u> button. This will add the new supplier to your list of suppliers and pre-select it for your current medication receipt entry.
- 3. You can see a confirmation that the entry has been made into the relevant register in the "Entry Log" section of the "Quick Book In Stock" popup. You can go back to step 2 and repeat the process if you have multiple medications that you wish to make entries of receipt for.

Recording supply of schedule 2 CDs

An entry of supply should be made in the relevant controlled drugs register when a schedule 2 CD is supplied to a named person or organisation. Commonly, supplies will be made against a prescription to patients, their representatives, or a delivery driver, but may also be made against a requisition by a healthcare professional or a pharmaceutical wholesaler (e.g. in the case of returned medication).

- Access/login to PharmCD access the PharmCD web app from the device web browser, and login using the premises account details (if not already logged in). Click the BOOK OUT button to launch the "Book Out Stock" popup window.
- 2. On the "Book Out Stock" popup, amend the "Entry Date" to the date of supplying the medication, then click the "Search Product" textbox and begin typing the name of the medication supplied; wait for the suggestions to appear below the textbox, and then click on the correct medication register.
 - a. <u>If supplying medication to a patient against a valid prescription</u>: click the "Search Patient" textbox and select the patient from the suggestions list. Then, if the prescriber shown in the "Prescriber" field



CD record keeping SOPs produced by **PharmCD**

Standard Operating Procedures for Controlled Drugs record keeping

(Page 5 of 12)

doesn't match the details of the prescriber of the prescription, then click the **CHANGE** button and search for the correct prescriber. Then, type in the "Person Collecting" texbox the details of the person collecting the medication. You can click the **COL** button to set the text as "Patient Collected" or the **DEL** button to set the text as "Delivered".

- i. If the patient does not appear in the list, then you can type their name and then press the **SEARCH** button to find them. For security reasons, PharmCD requires at least a partial surname of the patient, so you could find "John Smith" by searching for "Smith", "Smi" or "Jo Smi" but not "John". If you can find the correct patient, then select them from the suggestions list.
 - If the patient cannot be found by searching, then click the ADD NEW button to launch the "Add Patient" popup. Enter the patient details and then press the ADD PATIENT button to create the patient and pre-select them for the "Book Out Stock" popup.
- ii. If the prescriber cannot be found by searching, then click the ADD NEW button to launch the "Add Prescriber" popup. Enter the prescriber details and then press the ADD PRESCRIBER button to create the prescriber and pre-select them for the "Book Out Stock" popup.
- b. If supplying medication against a requisition: click the "Search Patient" textbox and select the healthcare professional requesting the CDs from the suggestions list. Then, if the prescriber shown in the "Prescriber" field doesn't match the details of the requisitioner of the requisition, then click the CHANGE button and search for the correct requisitioner. Then, type in the "Person Collecting" texbox the details of the person collecting the medication, and any reference number, plus a note to say that the CD supply is made via a requisition.
 - i. If the healthcare professional collecting the medication does not appear in the list of patients, then you can type their name and then press the **SEARCH** button to find them. For security reasons, PharmCD requires at least a partial surname of the patient or healthcare professional collecting, so you could find "John Smith" by searching for "Smith", "Smi" or "Jo Smi" but not "John". If you can find the correct person, then select them from the suggestions list.



Standard Operating Procedures for Controlled Drugs record keeping

(Page 6 of 12)

- If the person cannot be found by searching, then click the ADD NEW button to launch the "Add Patient" popup.
 Enter the person's details and then press the ADD PATIENT button to create the person and pre-select them for the "Book Out Stock" popup.
- ii. If the requisitioner cannot be found by searching, then click the ADD NEW button to launch the "Add Prescriber" popup. Enter the requisitioner details and then press the ADD PRESCRIBER button to create the requisitioner and pre-select them for the "Book Out Stock" popup.
- c. If supplying medication as a return to a supplier: click the "Search Patient" textbox and select the supplier that you are sending the CDs to from the suggestions list. Then, if the supplier shown in the "Prescriber" field doesn't match the details of the supplier, then click the CHANGE button and search for the correct supplier. Then, type in the "Person Collecting" texbox the details of the person collecting the medication, and any reference number, plus a note to say that the CD supply is made as a return to the supplier.
 - i. If the supplier does not appear in the list of patients, then you can type their name and then press the **SEARCH** button to find them. For security reasons, PharmCD requires at least a partial surname of the patient or healthcare professional collecting, so you could find "John Smith" by searching for "Smith", "Smi" or "Jo Smi" but not "John". If you can find the correct supplier, then select them from the suggestions list.
 - If the supplier cannot be found by searching, then click the ADD NEW button to launch the "Add Patient" popup.
 Enter the supplier's details and then press the ADD PATIENT button to create the supplier and pre-select them for the "Book Out Stock" popup.
 - ii. If the "prescriber" cannot be found by searching, then click the ADD NEW button to launch the "Add Prescriber" popup. Enter the supplier details and then press the ADD PRESCRIBER button to create the supplier and pre-select them for the "Book Out Stock" popup.
- 3. Adjust the "ID Requested?" and "ID Provided?" toggles to either yes or no depending on whether the person collecting the CDs had their ID requested



Standard Operating Procedures for Controlled Drugs record keeping

(Page 7 of 12)

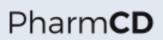
- or provided. In the "Enter Quantity" textbox, enter the quantity supplied. Finally, click the **BOOK OUT** button.
- **4.** You can see a confirmation that the entry has been made into the relevant register in the "Entry Log" section of the "Book Out Stock" popup. You can go back to step 2 and repeat the process if you have multiple medications that you wish to make entries of supply for.

Recording a stock balance check

Current NICE guidance for the management of controlled drugs recommends regular stock balance checks, at least weekly.

- Access/login to PharmCD access the PharmCD web app from the device web browser, and login using the premises account details (if not already logged in). Click the BALANCE CHECK button to launch the "Balance Check" popup window.
- 2. Registers are grouped by drug class; select a register and check to see if the balance in the PharmCD register matches the physical quantity of stock in the CD cupboard. Make sure to account for both the expired and unexpired stock, and ensure that the total quantity includes both expired and unexpired stock.
 - o If the quantity does match, then press the **CONFIRM** button.
 - If the quantity does not match:
 - i. If the total quantity of medication matches, but there is now a greater quantity of expired stock, then press the ADJUST button. Click the "Total Balance Inc. Expired" textbox and enter the total quantity, and click the "Expired" textbox and enter the quantity of expired medication. Then, press the CONFIRM CHANGES button.
 - ii. If the total quantity of medication does not match, and the medication is a liquid and the difference in actual quantity can be explained by an overage or minor spillage, then press the ADJUST button. Enter a reason for the quantity difference in the "Reason for Adjustment" textbox. Click the "Total Balance Inc. Expired" textbox and enter the total quantity, and click the "Expired" textbox and enter the quantity of expired medication. Then, press the CONFIRM CHANGES button.
 - iii. If there is a discrepancy in the PharmCD balance and the observed physical balance which cannot otherwise be explained,





Standard Operating Procedures for Controlled Drugs record keeping

(Page 8 of 12)

then refer to your SOP for investigating and recording CD discrepancies.

Recording a destruction of schedule 2 CDs in the presence of an authorised witness

The destruction of schedule 2 CDs belonging to the pharmacy or dispensary can only be done in the presence of an authorised witness.

- 1. Access/login to PharmCD access the PharmCD web app from the device web browser, and login using the premises account details (if not already logged in). Click the Auth. Witness button to launch the "Authorised Witness" Mode" popup window.
- 2. The authorised witness present should log in to their authorised witness account. If they don't have one, then they should click the **REGISTER** button to create a new account.
- 3. Once logged in, the authorised witness should click the **DESTROY** button to launch the "Destroy Stock" popup.
- 4. Once the medication has been denatured and witnessed by the authorised witness, then press the **DESTROY** button next to that medication. Amend the "Reason for destruction" with the reason for destroying the medication (such as "destruction of expired stock"), amend the "Quantity Destroyed" with the quantity of the medication that was denatured, amend the "Remaining Expired" with the new quantity of any expired medication, and amend the "New Balance Inc. Any Still Expired" with the new total quantity of the medication. Finally, press the CONFIRM DESTRUCTION button to make the record of that destruction in the relevant CD register.

Recording entries in the patient-returned CD register

It is considered good practice to keep a record of patient-returned controlled drugs and their subsequent denaturing.



CD record keeping SOPs produced by PharmCD

Standard Operating Procedures for Controlled Drugs record keeping

(Page 9 of 12)

- 1. Access/login to PharmCD access the PharmCD web app from the device web browser, and login using the premises account details (if not already logged in). Click the Menu dropdown button, and then click "Patient Returns".
- 2. In the "CD Return & Destruction Register" popup, amend the "Return Date" to the date of receiving the medication, then click the "Enter drug name" textbox and begin typing the name of the medication received; wait for the suggestions to appear below the textbox, and then click on the correct medication register. Click on the "Quantity" textbox and enter the quantity of medication received. Finally, press the ADD button to save this entry.
- 3. To mark a patient-returned medication as being denatured, press the **OPTIONS** dropdown button next to the medication, and then press "Destroy". In the "Destroy Returned Drug" popup, amend the "Destruction Date" to the date of denaturing the medication, then click the "Witnessed By:" textbox and enter the name of the witness. Finally, press the **DESTROY** button to mark that medication as denatured.

Making an amendment to a previous record

It is a legal requirement that entries in a CD register cannot be deleted, overwritten or updated. However, amendments to previous records are allowed, which maintains the previous record.

- Access/login to PharmCD access the PharmCD web app from the device web browser, and login using the premises account details (if not already logged in). Click the Register Search textbox, and type the name of the register that you'd like to amend. Click on the relevant register to open it.
- On the PharmCD register page, scroll through the register to locate the entry that you'd like to amend. Click on the entry, then press either the ADD COMMENT or MAKE ENTRY VOID button.
 - a. If you press the ADD COMMENT button, then enter a comment in the "Add Comment" textbox, then press the SAVE button. This will simply attach your comment to that entry, and may be useful for e.g. indicating where a part-supply has been made.
 - b. If you press the MAKE ENTRY VOID button, this will open the "Void Entry" popup. Enter a comment in the "Reason for marking entry as void:" textbox, and then press the CONFIRM VOID ENTRY button. This will mark the entry as void, meaning that it will still appear in the register but will be colour-coded as a void entry and will not count



Standard Operating Procedures for Controlled Drugs record keeping

(Page 10 of 12)

towards the running balance. This may be useful for e.g. voiding an entry which has been made in the wrong register, or voiding a previous supply which was for the incorrect quantity (in which case, a new entry will then have to be made with the correct quantity and other details).

Archiving a CD register

If a CD register is no longer in active use, it can be archived. This doesn't delete the register or it's entries, but does make it exempt from regular balance checking. A CD register can only be archived if the balance is zero.

- 1. Access/login to PharmCD access the PharmCD web app from the device web browser, and login using the premises account details (if not already logged in). Click the Register Search textbox, and type the name of the register that you'd like to archive. Click on the relevant register to open it
- 2. On the PharmCD register page, scroll to the bottom of the register and click the MARK INACTIVE button.

Merging patients

If multiple records for an individual patient have accidentally been created, then these records can be merged. Merging a **duplicate record** patient into a **master record** patient will <u>deactivate the duplicate record</u> so that they are no longer selectable when making new CD entries. When viewing reports for the master record patient, this will also include entries previously made against the duplicate record patient.

- 1. Access/login to PharmCD access the PharmCD web app from the device web browser, and login using the premises account details (if not already logged in). Click the Menu link at the top of the page, then select "Patients" from the dropdown list.
- 2. On the "Patients" page, enter a patient's name in the "Search Patient" field and then press the **SEARCH** button.
- 3. In the search results section, below the search bar, select the patient that you'd like to be the **duplicate record** and press the MERGE button next to their details.
- 4. On the "Merge Patients" popup, enter the name of the patient that you'd like to be the **master record** in the "Search for master record patient" field and then press the **SEARCH** button.



Standard Operating Procedures for Controlled Drugs record keeping

(Page 11 of 12)

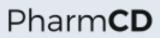
5. Click on the name of the desired master record in the search results beneath the search field, then click the MERGE PATIENTS button to finalise merging the patients.

Merging prescribers

If multiple records for an individual prescriber have accidentally been created, then these records can be merged. Merging a **duplicate record** prescriber into a **master record** prescriber will <u>deactivate the duplicate record</u> so that they are no longer selectable when making new CD entries. When viewing reports for the master record prescriber, this will also include entries previously made against the duplicate record prescriber.

- Access/login to PharmCD access the PharmCD web app from the device web browser, and login using the premises account details (if not already logged in). Click the Menu link at the top of the page, then select "Prescribers" from the dropdown list.
- 2. On the "Prescribers" page, enter a patient's name in the "Search Prescriber" field and then press the **SEARCH** button.
- 3. In the search results section, below the search bar, select the prescriber that you'd like to be the **duplicate record** and press the MERGE button next to their details.
- 4. On the "Merge Prescribers" popup, enter the name of the prescriber that you'd like to be the **master record** in the "Search for master record prescriber" field and then press the **SEARCH** button.
- 5. Click on the name of the desired master record in the search results beneath the search field, then click the MERGE PRESCRIBERS button to finalise merging the patients.





Standard Operating Procedures for Controlled Drugs record keeping

(Page 12 of 12)

SOP authorisation

	NAME	TITLE	SIGNATURE	DATE
EDITOR				
REVIEWER				
AUTHORISER				

Declaration of competence

Name	Signature*	Date

^{*}By signing this declaration you are confirming that:

- You have received the necessary training as outlined within this SOP'
- You have read and understood the information within this SOP'
- You will comply with the SOP at all times as directed.

