

Management of Controlled Drugs in Primary Care

GP Review Visit Template

Template plus additional copies of Part 3 should be brought to the visit by HSC staff.

Practice number:		Practice name:		HSC Pharmacist:	
Date of visit:					
List GPs, GP trainees, regular locums and whether each GP holds CD stock – score out if not applicable:					
Name	Holds CDs (✓)	Name	Holds CDs (✓)	Name	Holds CDs (✓)

Part 1: Review of GP Practice CD SOP/latest declaration/Compass

Does the practice have a CD SOP?	Y/N
For dispensing practices, does the practice have a CD SOP that covers the dispensing element (may be separate SOP or included in the main practice SOP)?	Y/N
Does the CD SOP(s) include procedures for the following areas as required by the AO regulations? <ul style="list-style-type: none"> • Access to CDs (including use of HS21S by GPs and locums) • Storage and transportation • Security • Disposal and destruction (including any patient returns) • Who to alert if complications arise • Record keeping • Prescribing, supply, administration and clinical monitoring of CDs 	Y/N Y/N Y/N Y/N Y/N Y/N Y/N
Does the CD SOP(s) include procedures for other areas relevant to the practice? <i>Note headings and any points for discussion at visit.</i>	Y/N

Is the practice copy of the CD SOP(s) signed by all CD prescribers including regular locums and non-medical prescribers?	Y/N
Any points for discussion following review of the latest CD declaration? <i>Note below.</i>	Y/N
Any points for discussion following review of COMPASS data & stock requisitions? <i>Note below.</i>	Y/N
Any other notes for discussion at visit:	

Recommendations/actions agreed at visit:	Timescale:

Part 2: Review of CD Management within the Practice

Part 2a: Practice Controlled Drugs^a declaration ALL QUESTIONS MUST BE ANSWERED

Practice number: Date of visit:	Practice name:	HSC Pharmacist:
Type of GMS service provided		
Standard GMS	OOHs provider	Dispensing Doctor
Procedures	Y/N	<i>Comments</i>
<p>Do you have written standard operating procedures or written policies covering the complete area of handling and management of CDs, appropriate to the activities carried out within your practice, and as required by the Accountable Officer regulations (see Part 1). This applies to all CDs Schedule 2-5.</p> <p><i>The HSC PSP will request a copy of the practice SOP for review in advance of the visit.</i></p>		
Procedures	Y/N	
Do you have in place a local procedure for identifying, dealing with and learning from significant events** involving CDs?		<i>Please outline brief details</i>
Do you have appropriate procedures for the initial and continuing training and development of all staff who are involved in the prescribing, handling, supply, storage, administration and disposal of CDs?		<i>Please outline brief details</i>
Are all CD prescribers (including regular locums and non-medical prescribers) aware of the practice CD SOP and trained as necessary?		<i>Comments</i>
Do you have a prescription security protocol?		<i>Comments</i>
Does each prescriber hold their own personal supply of CD drugs (where needed) and CD register?		<i>Please outline brief details</i>

Are any CDs held centrally for use by GPs e.g. in the treatment room (all Schedules, includes codeine and benzodiazepines / Z drugs)		<i>Please outline brief details</i>
Are yellow copies of stock orders kept for 2 years?		<i>Please outline brief details of storage arrangements</i>
Is there a process for expiry date checks on CD stock?		<i>Please outline brief details of process</i>
Complaints/Concerns/Incidents regarding prescribing, supply and/or administration of Controlled Drugs	Y/N	
Have there been any patient or carer complaints* involving CDs within the last two years?		<i>Please outline brief details</i>
Do you have any concerns about particular patients' use of CDs?		<i>Please outline brief details</i>
Have there been any concerns expressed by colleagues, police, drugs misuse services or others about unusual, excessive or inappropriate use of CDs by patients?		<i>Please outline brief details</i>
Have you identified any discrepancies between register running balances and actual CDs stored in the last 2 years?		<i>Please outline brief details</i>
Have there been any other significant events** involving CDs?		<i>Please outline brief details</i>
Prescribing	Y/N	
Are there any special factors which influence the prescribing or use of CDs by the Practice? (For example, patient demographics, involvement with Nursing Homes/Hospices, prescribing for addicts.)		<i>Please outline brief details</i>
Are there any restrictions on the possession, administration or prescribing of controlled drugs on any of the healthcare professionals in your practice?		<i>Please outline brief details</i>

Are all prescriptions that are written for CDs limited to a maximum 30 day supply?		
Do you prescribe CDs to addicts? (a) routinely (b) as part of a substance misuse service		<i>Please outline brief details</i>
Do you use private prescriptions to prescribe CDs? If yes, do you use PCD1 forms?		<i>Please outline brief details</i>

^aThis refers to CDs of ALL schedules (i.e. Schedules 1-5)

*This includes complaints about prescribing inappropriate doses and/or appropriate medicines.

**Significant event includes any incident where a patient is harmed or nearly harmed and includes 'near misses', when things almost go wrong.

For Dispensing Doctors please also complete part 2b

**Part 2b – Review of Dispensary CD Management (Schedule 2-5)
Dispensing Practices only**

Responsibilities	
There is a written standard operating procedure covering the dispensing of CDs (Schedule 2-5). <i>The HSC PSP will request a copy of the practice SOP for review in advance of the visit.</i>	Y/N
Responsible GP: A GP responsible for CD management within the practice. This person is responsible for ensuring the information contained within the SOP is accurate and complies with current CD regulations as well as ensuring that the SOP is implemented. Doctors are the only members of the practice who can legally possess CDs. The practice should therefore designate a GP and deputy, who take responsibility for all aspects of CD usage, including ordering, recording, storage, dispensing and monitoring. The responsible GP must ensure that all staff receive appropriate training.	The GP responsible for CD management within the practice is: Insert name, and name of deputy
The following staff have been authorised to receive, handle and dispense CDs and have access to safe storage facilities.	Authorised staff: Insert name(s)
There are systems in place to make sure that there is always at least one such authorised staff member on duty.	Describe system
The following staff have been authorised to destroy or witness the destruction of patient-returned CDs.	Authorised staff: Insert name(s)
<i>It is the responsibility of those working to the procedures to highlight to the Responsible GP any deficiencies in the SOP.</i>	
Ordering Stock	
a) CDs are ordered for: Specify use (e.g. dispensary stock)	
b) CDs are ordered from: Specify wholesaler(s) and location	
c) The following GPs may sign CD orders: Insert name(s) of all GPs who may sign orders for CDs	

<p>d) The following process is in place to order CDs: Specify practice process, including details of who is authorised to prepare orders, who signs, copies taken, storage of copies and reconciliation of received stock</p>	
<p>e) The following process is followed if a GP requires stock for their bag: Specify practice process, including details of record keeping and audit trail (Dispensing doctors can't dispense stock requisitions as they have no Wholesale Dealer's licence. If a dispensing doctor requires stock for their bag (as advised by the Dispensing Doctors Association) they access this stock direct from the dispensary stock and log it from dispensary register into their personal CD register (for Sch 2 CDs). This transfer of stock and completion of the register is witnessed by another member of practice staff).</p>	
<p>Receipt of Schedule 2 and 3 CDs</p>	
<p>a) CDs should be received by dispensary staff or given immediately to: Specify names of all who may accept deliveries of CDs</p>	
<p>b) CDs are immediately stored in a locked receptacle e.g. CD cabinet, in dispensary. Specify all locations and what process must be followed in the event of being unable to immediately access the correct receptacle</p>	
<p>c) An entry is made in the CD Register by the recipient on the day of receipt or the day following at the latest. Specify all who may add details to CD Register(s)</p>	
<p>Safe Storage of CDs This applies to all Schedule 2 drugs, e.g. diamorphine, morphine, and certain Schedule 3 drugs (e.g buprenorphine and temazepam).</p>	
<p>a) All undispensed and dispensed Schedule</p>	

<p>2 CDs, including buprenorphine and temazepam as noted above are stored in a locked receptacle e.g. CD cabinet.</p> <p>Specify all storage locations</p>	
<p>b) Are storage and security arrangements adequate for all other CDs (Schedules 3-5)? This includes CDs that are dispensed and awaiting collection.</p> <p>Specify all storage locations</p>	
<p>c) The nominated key holder(s) or those permitted to access the locked receptacle is/are:</p> <p>Specify all persons responsible</p>	
<p>d) Key/access control arrangements:</p> <p>Detail how practice controls keys to storage facilities and reduces access by unauthorised persons including arrangements when practice closed.</p>	
<p>e) All CD Registers should be stored at the premises to which they relate.</p> <p>Describe where dispensary CD Register is held</p>	
<p>DISPENSING GOOD PRACTICE: <i>The practice (and partners) carries vicarious liability for errors made, or for any breach of the law. A dispenser or other dispensing doctor employee would not normally be expected to dispense a Schedule 2 or 3 controlled drug without first checking the dispensed items with a doctor. The Dispensing Doctor's Association's (DDA) Guidelines for dispensing doctors state that 'the doctor should check all prescriptions for controlled drugs'.</i></p>	
<p>a) The following staff have been authorised to dispense CDs:</p> <p>Enter names</p>	
<p>b) There are checking processes in place for CDs, including processes for labelling, dispensing, checking and storage of completed prescriptions.</p> <p>Detail practice process and personnel involved</p> <p>(GPs should not be involved in dispensing and checking controlled drugs issued for their bag. This should be done by another GP in the practice and a full audit trail kept).</p>	

c) All dispensed CDs are appropriately labelled.	
d) CDs are stored securely after dispensing prior to collection. Detail practice process	
e) Register must be completed for all Schedule 2 CD dispensing. Detail practice process including who may complete the register	
f) Proof of identity check undertaken and recorded for collection of schedule 2 CDs Detail practice process	
g) GOOD PRACTICE: Patients and carers are advised on the safe storage of CDs in the home, the dangers of stockpiling and the importance of returning unused CDs to a pharmacy.	
Stock Checks	
a) Physical checks of stock Schedule 2 CDs are carried out regularly (at least monthly) to ensure all stock is accounted for and in date. <u>These are recorded.</u> Detail practice process for dispensary stock checks including frequency of checks	
b) Any discrepancies are investigated fully and logged. Detail practice process	
c) Unresolved discrepancies are reported to the person responsible for CDs in the practice, the DH MRG and HSCB CD Accountable Officer. Detail practice process including timescales	
d) Date-checking/Out of date stock procedure: Detail practice process including how stock found to be out of date is clearly marked and segregated from in date stock until arrangements can be made to have the out of date stock destroyed	

Destruction and Disposal of CDs

DDA Guidelines state that:

- *patients should return obsolete /out of date medicines (patient returns) to the dispensary from where it was dispensed*
- *dispensing practices should destroy/dispose of their own obsolete /out of date medicines - in line with guidance.*

a) All CDs, whether stock or patient returns, in schedule 2, 3 and 4 (Part 1) will be denatured before disposal. Schedule 4 (Part 2) and 5 CDs will be placed directly into the appropriate pharmaceutical waste bin for disposal.	Detail practice process.
b) Any dispensary stock of Schedule 2 CDs past their expiry date or otherwise unsuitable for use will only be destroyed in presence of person specifically authorised to witness CD destruction.	Detail practice process
c) Schedule 2 CDs awaiting destruction will be retained on-site in a suitably secure receptacle, e.g. CD cabinet, appropriately labelled and clearly segregated from all other stock. All such CDs will continue to be recorded in the appropriate CD Register.	Detail practice process.
d) In the presence of the authorised witness, a competent member of staff at the Practice will perform the destruction of Schedule 2 CD stock.	The competent staff member(s) permitted to destroy stock CDs is/are: Insert name(s)
e) Schedule 3 and 4 (Part 1) CDs which are out of date or otherwise unfit for use may be destroyed by competent authorised members of staff.	Detail practice process.
f) Details of CDs returned by patients or their representatives for disposal will be recorded in a patient returns register/book	Detail process
g) Destruction of patient returned CDs does not require the attendance of an Authorised Witness. Where a practice has received patient returned CDs, destruction will be undertaken as soon as is practicable within the Practice by two competent members of staff. This will be recorded in a separate book kept for that purpose (patient returns register/book).	Members of staff permitted to destroy patient returned CDs are: Insert name(s) of staff competent to carry out this process if required

h) Schedule 2, 3 and 4 (Part 1) CDs will only be destroyed by being placed into a commercially available denaturing kit. The Practice will ensure that denaturing kits are available on-site for this purpose.	Detail process		
i) When destruction is completed, the name, position, and signature of the person destroying the CDs (and the witness) will be added to the CD Register or patient returns register/book, along with the date of destruction.	Detail process		
j) Denaturing kits containing destroyed CDs must only be disposed of in the appropriate pharmaceutical waste bins.	Detail process		
Incidents, Near Misses or Concerns involving CDs			
Name	Role	Timescale	Yes/No (and any comments)
<i>Insert Name</i>	Responsible person within practice for CDs	Immediately made aware	
<i>Insert Name</i>	Deputy	When responsible person not available	
Mr Joe Brogan	HS Controlled Drugs Accountable Officer	Made aware via Pharmacy Adviser	
Training			
a) All staff carrying out duties within the dispensary receive initial and ongoing training on the management and use of CDs, including after CD dispensing incidents, in addition to specific training applicable to the dispensing process.	Detail process		

Physical Check of CD Register

CD Register meets legal requirements, eg bound book, correct headings	Y/N
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Review CD Register pages for stock currently held by dispensary. If no Schedule 2 stock is currently held, check pages for stock held/dispensed within the past year.

Records of receipts and supplies correctly entered	Y/ N	Running balances recorded	Y/N
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Errors/corrections as marginal footnotes and dated/initialled	Y/N	CD register balances with actual stock held	Y/N
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Pharmacist signed and dated under last entry for each drug strength (page) reviewed. i.e. 'CD visit undertaken by (PSPs name) on (date)'	Y/N
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Parts 2a and 2b

Notes/queries/feedback at visit:

Recommendations/actions agreed at visit:	Timescale:

2c - Declaration To Be Completed By All Practices

I declare that to the best of my knowledge and belief that the handling, management and use of all controlled drugs at these premises complies with the provisions of the Misuse of Drugs Act 1971, its associated regulations and the Health Act 2006 and its associated controlled drugs regulations.

I undertake to address any issues raised or identified by the CD review visit, including those noted in Part 3, as appropriate and within the time frame specified by HS staff.

Signed by practice manager and Governance Lead for practice (or designated GP partner) / Medical Manager for OOH centre:

Name (please print)	Signature	Registration Number (if applicable)	Position within Organisation	Date

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Part 3: Review of CD stock & CD registers for each GP

GP name: _____ Date of visit _____

Record of stock of all CDs (Schedule 2-5) ordered by the GP in last 15 months:
(Use PID scans and practice-held yellow copies of HS21S as guide. Enter PID information in advance of visit)

Date stock ordered: _____

Item: _____

GP using own stock requisitions	Y/N	Stock ordered as full pack	Y/N
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CD Stock review:

List CD stock currently held by GP:

Item: _____

Expiry date: _____

CDs & CD register stored securely	Y/N	Stock type appropriate e.g. forms required for immediate treatment	Y/N
CDs & CD register stored separately	Y/N		
CDs stored in their original pack	Y/N	Stock levels appropriate e.g. not excessive	Y/N
CD stock in date	Y/N	Patient returns held	Y/N
Stock ordered and supplied reconcile with stock held (Schedule 2)	Y/N	Current stock corresponds with CD register	Y/N
Non-schedule 2 stock reviewed	Y/N	Naloxone held	Y/N
Evidence of regular stock checks	Y/N	Evidence of stock expiry checks	Y/N

CD Register review – Schedule 2 CDs

Bound book & column headings comply with regulations (see Appendix 4)	Y/N	Section for each drug	Y/N
Page for each form and strength of drug	Y/N	Entries are in ink & chronological order	Y/N
Errors/corrections are marginal footnotes	Y/N	Corrections dated & initialled	Y/N

Records of receipt of CDs:

Date entered is recorded	Y/N	Name & address of supplier is recorded	Y/N
Amount obtained is recorded	Y/N	Form obtained is recorded	Y/N
Running balance is recorded	Y/N		
Records of supplies/administration:			
Date of supply is recorded	Y/N	Name & address of person supplied is recorded	Y/N
Authority to possess is recorded	Y/N	Amount supplied is recorded	Y/N
Form supplied is recorded	Y/N	Running balance is recorded	Y/N
Patterns of supply/administration are appropriate	Y/N	Record/entry that out of date stock is returned to pharmacy	Y/N

Pharmacist signed and dated under last entry for each drug strength (page) reviewed. i.e. 'CD visit undertaken by (PSPs name) on (date)'	Y/N
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GP name:	
Notes/queries/feedback at visit:	
Recommendations/actions agreed at visit:	Timescale:

Part 4: Final Summary (HSCB office use only)

Practice name:		Practice Number:	
Date of visit:			
	Notes	Date	Any additional Notes
Second/follow-up visit required prior to completing report	Y/N		
Report completed including details of queries and actions agreed, if any.	Y/N		
Follow-up visit required after sending report	Y/N		
Written confirmation received of actions/recommendations completed	Y/N (if N – complete next row)		
Practice reminded (email and phone as necessary – as per SOP guide) and no response after >8 weeks approx. since receipt of report – discussed with PSP Lead and way forward agreed.			
Reviewed and Filed by HSC Pharmacist:			
Name:		Date:	

Any Post Visit Notes/Comments following the visit: