Queensland Health

Pharmacy Inquiry Response Program

Community pharmacy compliance survey

To be completed by inspector during the compliance site visit

Inspector's Name	
Date of survey	
Name pharmacist in charge	
Consent to enter	☐ Y ☐ N Document reason in Section 7 if consent not provided
AHPRA registration type	☐ General ☐ Provisional ☐ Student ☐ Other
Time – start/finish	

1.0 Pharmacy Information		
1.1 Pharmacy Details		
Name of Pharmacy:		
Address:		
Contact number:		
Email address:		
Preferred communication:	☐ Email	☐ Post
1.2 Pharmacy Owner's Details (if known)		
Owner name/s:		
Contact number/s:		
1.3 Accreditation		
Accreditation agency:		
Expiry:		

2.0 Controlled Drugs (CD)

2.1 Stock Checks - HDPR s88(1)

a) When was the last stock check recorded in CD record? *(Sight CD record)*

☐ Routine ☐ Change in managing pharmacist >7 days ☐ Other

Comments:

2.2 Reporting a CD discrepancy - HDPR s88(2)

b) Has an irreconcilable/unaccountable CD discrepancy been identified within the last 12 months?	☐ Y ☐ N

If yes, who was it reported to:

2.3 CDs for destruction – HDPR s86 and s130

c) Where/how are expired and patient returned CDs disposed and destroyed? (Sight evidence).

Name of document, version and revision date:

d) Is the transaction for the return of patients own CDs and expired CDs entered in CD record in accordance with the legislation? *(Sight CD record)*	☐ Y ☐ N ☐ N/A

If no, comment:

2.4 CD record transactions – HDPR s86-87, s126

e) Are transactions documented in the CD record in accordance with legislation?
(Review a sample of 3 random transactions - record in table below)

Transaction date	Transaction Type	Complies with legislation
		☐ Y ☐ N
		☐ Y ☐ N
		☐ Y ☐ N

Comment on any issues with transactions:

2.5 Storage of completed CD records – HDPR s133	
☐ Paper based records	☐ Electronic records
f) How long are the CD records stored once closed off?	
g) Where are the completed electronic CD records backed up?	
Comments:	

2.6 CD storage – HDPR s119	
h) Is the safe located in a safe and secure area of the pharmacy?	☐ Y ☐ N
i) Is the safe locked on inspection?	☐ Y ☐ N
j) Is the key/combination secure and only accessible by authorised persons?	☐ Y ☐ N
k) Are all CDs stored in the safe?	☐ Y ☐ N
Comments:	

2.7 Procurement of CD – HDPR s89, s133, s200	
l) How long are the original CD invoice order confirmation stored after receipt?	
m) Random audit: audit 3 separate random original CD orders, CD invoices and reconcile with CD record transactions and confirmation of receipt returned to the supplier *(record details in below table).*	

PO Number	**Wholesaler**	**Date Drugs Received**	**Date confirmation returned to Wholesaler**	**CD record transaction is correct**
				☐ Y ☐ N
				☐ Y ☐ N
				☐ Y ☐ N
Comments:				

Section 2.0 Controlled Drugs	Issues Identified ☐ Y ☐ N

3.0 Restricted Drugs (RDs – Schedule 4), Schedule 2, 3, 5 and 6	
3.1 Storage and access to RDs – HDPR s211	
n) Are all RDs stored in an area not accessible to the public?	☐ Y ☐ N
3.2 Storage and access to Schedule 2 and 3 – HDPR s284	
o) Are all Schedule 2 and 3 poisons stored in an area not accessible to the public?	☐ Y ☐ N
3.3 Storage and access to Schedule 5 and 6 – HDPR s284	
p) Are all Schedule 5 and 6 poisons kept out of reach of children?	☐ Y ☐ N
Comments:	

Section 3.0 Restricted Drugs, Schedule 2, 3, 5 and 6	Issues Identified ☐ Y ☐ N

4.0 Dispensing and supply		
4.1 Dispensing and emergency sale – HDPR as below (s4A, s81A, s194 and s273A)		
q) For electronically recorded transactions what are the current backup processes in the event of a temporary and/or permanent adverse event?		☐ N/A
Provide details:		
r) Do you have a documented guideline or an approved Standard outlining the process for dispensing?		☐ Y ☐ N
s) Do you supply medicines to people under the Emergency Sale provisions?		☐ Y ☐ N
t) How many days' supply is given for the Emergency Sale of RDs?	Amount given	☐ N/A
u) Are there any other ways the pharmacy receives prescriptions?		
Provide details:		

4.2 Supply – HDPR s47, s90, s93, s141, s171, s201, s203	
v) Does the pharmacy supply medications to other agencies, entities or service providers, or store medications in another location?	☐ Y ☐ N
w) How are drugs supplied to other agencies (i.e. by purchase order or goodwill transfer)?	
Provide details:	

Section 4.0 Dispensing and Supply	**Issues Identified** ☐ **Y** ☐ **N**

5.0 Quality Standards for Dispensing

5.1 Quality Health Programs and Services - HDPR s4A, s78A, HR s27, s28

x) What Quality Health Programs and Services does your pharmacy offer?

- ☐ Opioid Treatment Program
- ☐ Needle and Syringe Program
- ☐ Smoking Cessation Program
- ☐ Dose Administration Aids
- ☐ Vaccination Services in Pharmacy
- ☐ Other

y) Does the pharmacy prepare and dispense compounded products? ***If yes, refer to Appendix A***	☐ Y ☐ N

6.0 Poisons/Pseudoephedrine

6.1 Supply and recording pseudoephedrine sales – HDPR s277 and s285A

z) Are products that contain pseudoephedrine stocked/sold?	☐ Y ☐ N
aa) What program is used for reporting the sale of pseudoephedrine?	
Provide details:	

Section 6 Poisons/Pseudoephedrine	**Issues Identified** ☐ **Y** ☐ **N**

7.0 Comments and/or recommendations			
Overall issues rating: ****Explain that although nil issues may have been identified today, there may be issues that were not identified during the survey**			
Inspector's signature:		**Date:**	
For office use only – select public health unit where pharmacy is located:	Choose an item...		

Community pharmacy compliance survey Appendix A – Extemporaneous compounding

As defined by the Pharmacy Board of Australia (PBA), compounding means the preparation and supply of a single 'unit of issue' of a therapeutic product that is intended for immediate use by a specific patient in response to an identified need.

Simple – includes all products except the preparation of sterile or complex products, such as hormones or cytotoxics. Formulations for preparation are routinely from the Australian Pharmaceutical Formulary (APF).

Complex – includes products which require or involve specific competencies, equipment, processes or facilities. It includes complex and sterile products.

Name of Pharmacy:		
1.1 Simple and Complex compounding HR s27-29 and PBA		
a) Does the pharmacy provide simple and/or complex/sterile compounding services?	Simple ☐	Complex ☐
	Yes	**No**
b) Does the pharmacy sell compounded products interstate?	☐	☐
c) Does the pharmacy sell compounding products in quantities larger than a single unit?	☐	☐
d) Does the pharmacy refer/receive compounding scripts to/from another pharmacy?	☐	☐
e) Is a separate record available to document compounded products?	☐	☐
f) Is information recorded in the compounding worksheet/book in accordance with the current APF (document in below table)?	☐	☐

Sight 3 random transactions	Confirm the documented information in the compounding worksheet/ book.				
Transaction ID number	**Ingredients**	**Batch number**	**Expiry**	**Process**	**Label**
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐

1.2 Sterile compounding HR s27-29

g) When was the equipment and air handling facilities last tested? (Must be maintained and tested in accordance with AS/NZS ISO 14644 – test based on risk assessment, or at least annually).	Date last tested:

h) Sight the pharmacy's standard operating procedures for:

- ☐ Dispensing
- ☐ Training of staff involved in sterile compounding
- ☐ Cleaning of compounding area
- ☐ Spillage, storage and disposal of waste
- ☐ Servicing of equipment
- ☐ Quality assurance of compounding activities
- ☐ Packing, labelling, handling and storage

i) Are the standard operating procedures reviewed yearly? *Sight evidence*	☐ Y	☐ N

Simple and Complex compounding	**Issues identified:**	☐ Y	☐ N

Comments and/or recommendations