PHARMACY QUALITY AUDIT 4
Community Pharmacy Audit Tool

version 1.0

integrated requirements of

Ministry of Health and
District Health Boards

Pharmacy Trading Name		**Additional Services:**
Pharmacy Address		☐ Needle Syringe Exchange Programme ☐ Online Pharmacy Services www._____ ☐ Pharmacy Depot ☐ Compliance Packaging ☐ Automated Packing & Dispensing ☐ Clozapine Dispensing ☐ Opioid Substitution Treatment ☐ Aseptic Dispensing of Sterile Products
Pharmacy Phone Number		
Proprietor/ Pharmacy Manager		
Date of audit		
Auditor(s)		
CAR forms issued:		

Glossary

APC	Annual Practising Certificate
CAR	Corrective Action Request
CD	Controlled drug
CoE	Pharmacy Council Code of Ethics 2004
CRCs	Child resistant closures
ECP	Emergency Contraceptive Pill
GMP	Good manufacturing practice
HDC	Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996
HIPC	Health Information Privacy Code 1994 and amendments
HPCAA	Health Practitioners Competence Assurance Act 2003
HR	Health (Retention of Health Information) Regulations 1996
MA	Medicines Act 1981
MoDA	Misuse of Drugs Act 1975
MoDR	Misuse of Drugs Regulations 1977
MR	Medicines Regulations 1984
OST	Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008
OTC	Over-the-counter
PSA	Pharmacy Services Agreement (March 2010)
PSS	NZS 8134.7:2010 Health and Disability Services Pharmacy Services Standard
SAB	Still air box
SMM	Safe Management of Medicines: A Guide for Managers of Old People's Homes and Residential Care Facilities (September 2007)
SOPs	Standard Operating Procedures

Audit Framework

- During the site audit each audit criterion is assigned a level of attainment:

Level of attainment	
CI	Continued Improvement
FA	Fully Attained
PA	Partial Attainment
UN	Unattained
NA	Not Applicable

- Audit criterion that are **PA** or **UA** are assigned a level of risk:

Level of risk	
C	Critical
H	High
M	Moderate
L	Low
N	Negligible

- Corrective action request forms (CARs) are completed by the auditor for **critical** and **high** risks.

Note
Whilst this audit tool references specific aspects of NZS 8134.7:2010 Health and Disability Services Pharmacy Services Standard, the whole standard is applicable to pharmacy audits.

SECTION A: ORGANISATION

A.1 Licence to Operate Pharmacy

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
A.1.1	**Is the current Licence to Operate Pharmacy on display to consumers?** *MA 54(1); PSA Schedule C1 Base Pharmacy Services 7.3*			
A.1.2	**Are the details on the licence accurate?** • **site details** • **responsible persons** • **additional conditions** *MA 51(1)(d); MR 48A*			
A.1.3	**Is the pharmacy complying with additional conditions (c) onwards, if any, imposed on the licence?** *MA 52(3)*			
A.1.4	**Are the pharmaceutical services provided by the organisation managed by a responsible person who is a pharmacist with authority, accountability, competency, and responsibility for the provision of services?** *PSS 2.2.1*			
A.1.5	**Is the charge pharmacist identifiable at all times when pharmaceutical services are provided?** *MA 42(A); PSS 2.2.2; CoE 1.10*			

SECTION A: ORGANISATION

A.2 Staff Qualifications

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
A.2.1	**Do all pharmacists working in the dispensary have a current Annual Practising Certificate (APC)? Are there conditions?** *HPCAA 8(1); PSS 2.5.2*			
A.2.2	**Are all other staff working in the dispensary suitably qualified or in a registered training programme (eg, technicians, dispensary assistants, intern pharmacists)?** *MR 42(1),42(1A); PSS 2.5,5.2.5; PSA G9(b), Schedule C1 Base Pharmacy Services 7.5*			
A.2.3	**Is there appropriate supervision of trainees and other relevant support staff?** *PSA G9(c,d)*			

SECTION A: ORGANISATION

A.3 Consumer Rights & Health Information

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
A.3.1	**Do consumers receive services in accordance with consumer rights legislation?** *PSS 1.1; PSA G6.1* **Are consumers treated with respect and receive services in a manner that has regard for their dignity, privacy and independence?** *PSS 1.3; PSA G6.2* **Do consumers who identify as Māori have their health and disability needs met in a manner that respects and acknowledges their individual and cultural values and beliefs?** *PSS 1.4*			
A.3.2	**How are consumers informed of their rights? Is the *Code of Health and Disability Consumers' Rights* clearly displayed and easily accessible to all consumers?** *PSS 1.2; HDC Schedule 1(3)(a),2; PSA G6.1*			
A.3.3	**Are all staff aware of the confidentiality of health information?** • **that no unauthorised use may be made of it?** • **the circumstances that allow the release of information by the Privacy Code?** *PSS 2.7.5; HIPC rules 6,10,11; PSA G6.5; CoE 1.8*			
A.3.4	**Is information entered into the pharmacy information management system in an accurate and timely manner, appropriate to the service type and setting?** *PSS 2.7.1; HIPC rules 4,8; PSA Schedule C1 7.1(c)*			
A.3.5	**Is information of a private or personal nature maintained in a secure manner that is not publicly accessible or observable?** • **if the pharmacy has an internet connection, has provision been made to ensure the security of confidential health information?** • **are electronic prescription records maintained for a minimum of 10 years? Where?** • **are there appropriate back-up and disaster recovery procedures to protect against the loss of information?** • **storage of medicines awaiting collection?** *MR 42(3)(l),54A,57,58; HR 5,6; PSS 2.7.4,2.7.6; HIPC rules 5,9; PSA G13.2*			

SECTION B: CONTROLLED DRUGS

B.1 Storage of Controlled Drugs

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
B.1.1	**Are controlled drugs stored in a safe or substantial metal cabinet, which forms part of, or is firmly fixed to the premises? If the safe is constructed of steel, does the safe comply with the Requirements for the Custody of Controlled Drugs in Steel Safes?** *MoDR 28;Requirements for the Custody of Controlled Drugs in Steel Safes*			
B.1.2	**Are all reasonable steps taken to ensure that controlled drugs are secure at all times?** • **location of safe?** • **locked when not in immediate use?** *MoDR 28*			

SECTION B: CONTROLLED DRUGS

B.2 Records of Controlled Drugs

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
B.2.1	**Is an approved form of controlled drugs register maintained?** *MoDR 37*			
B.2.2	**Is a separate page used for each strength and form of controlled drug?** *MoDR 37(2)(a)*			
B.2.3	**Are all transactions recorded within 1 business day?** *MoDR 40(1,3)*			
B.2.4	**Are any alterations made in the approved fashion?** *MoDR 40(2,4)*			
B.2.5	**Is half yearly stock taking performed as at the close of business on the 30th June and 31st December every year?** *MoDR 43(1,2)*			
B.2.6	**After the half yearly stocktaking are all stock records, quantity stock accounts and explanations or variations entered into the book no later than 14 days after these dates?** *MoDR 43(1,2)*			

SECTION B: CONTROLLED DRUGS

B.2 Records of Controlled Drugs (continued)

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
B.2.7	**Are records complete, accurate, current, legible and indelible?** *MoDR 37,40,43*			

Controlled Drug	Register Page	Running balance	Physical stock	Notes

B.2.8	**Are controlled drug prescriptions and register(s) retained for at least 4 years? In a neat and orderly manner? On the premises?** *MoDR 33*			
B.2.9	**Are destructions and records of returns recorded in the controlled drugs register?** *MoDR 40(1)*			
B.2.10	**Are obsolete or returned controlled drugs destroyed in an appropriate manner?**			

SECTION C: DISPENSING, COMPOUNDING, REPACKING & BATCH PREPARATION

C.1 Dispensing Procedures

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
C.1.1	**Have SOPs for the dispensing and supply of pharmaceutical products been developed, documented and approved by the pharmacist(s) who has/have effective control as complying with legislative requirements?** *MR 42; MoDR 31; PSS 5.2.1,5.2.2*			
C.1.2	**Are secure, accurate and orderly records of prescriptions maintained?** *MR 42(3)(l), 57,58; MoDR 33; PSS 5.2.3(c)*			
C.1.3	**Is the use of generic medicine substitution controlled by agreed and documented policies? Are up-to-date substitution agreements maintained?** *MR 42(4); PSS 5.2.6; PSA Schedule C1 3.2*			

SECTION C: DISPENSING, COMPOUNDING, REPACKING & BATCH PREPARATION

C.2 Dispensing Practice

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
C.2.1	**Are all dispensing activities undertaken or directly supervised by a pharmacist?** *MR 42(1),42(1A); PSS 5.2.3(a); CoE 3.8*			
C.2.2	**Does a pharmacist interpret and evaluate prescriptions for correctness and completeness, verify their authenticity and appropriateness?** *MR 39,41; MoDR 29,32(1); PSS 5.2.4; CoE 2.6*			
C.2.3	**Is a signed authorisation received prior to dispensing? How are original prescriptions to verify those received by telephone, fax or other electronic means handled?** • **obtained promptly as required by legislation** • **reviewed by pharmacist** • **matched and checked against telephone/fax prescription** *MR 40A,41; MoDR 34; PSS 5.2.3(b)*			
C.2.4	**Are emergency supplies of medicines made in accordance with legislative requirements?** *MR 44(m)*			

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
C.2.5	**When a pharmacist is unable to dispense a prescription, is the consumer assisted to obtain the medicine from another source?** *PSS 5.2.3(h)*			
C.2.6	**Are suitable and appropriate containers used for the packaging of pharmaceutical products?** • how are the containers stored? • are the containers clean? • are safety containers used (where required)? *MA 44; MR 35,37; PSS 5.2.3(d),5.12.9,5.21.1,5.21.2; CoE 3.17*			
C.2.7	**Are containers labelled with information for the consumer that meets legal and professional requirements, accurately reflecting the prescribers instructions including:** • quality of print • size of print • no abbreviations • cautionary & advisory information included • 'External Use Only'/'Not to be Taken' on external products *MR 12, 17, 18, 23; PSS 5.2.3(e)*			
C.2.8	**Do prescription forms (including originals, repeats & owes) clearly record who dispensed the prescription and the pharmacist responsible for the final check for completeness and accuracy?** *PSS 5.2.3(f); CoE 3.9*			
C.2.9	**Are proper controls used to ensure that the medicines prescribed are received (including delivery) by the intended person?** *PSS 5.2.3(g)*			
C.2.10	**Is all essential professional advice and counselling provided to consumers in a private & confidential manner? Are all reasonable steps taken to ensure that they have a sufficient knowledge to ensure optimal therapy?** *PSS 1.9.2; PSA G6.2,G6.5,Schedule C1 7.1(b); CoE 3.4*			

SECTION C: DISPENSING, COMPOUNDING, REPACKING & BATCH PREPARATION

C.3 Pharmacy Equipment

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
C.3.1	**Can the pharmacy demonstrate ready access to appropriate reference resources, including:** • ready reference of concise information on individual medicines • reference containing broad information on individual medicines • therapeutics or clinical pharmacy text • drug interactions reference • drugs in pregnancy and breast feeding references • over the counter medicines references • herbal medicines reference • medical dictionary • NZS 8134.7 Health and Disability Services Pharmacy Services • Health Information Privacy Code 1994 • Pharmacy Council Code of Ethics *MA 51(1)(e); PSA G10(b)*			
C.3.2	**Can the pharmacy demonstrate ready access to legislation (including amendments) affecting pharmacy practice?** *MA 51(1)(e); PSA G10(b)*			
C.3.3	**Does the pharmacy maintain sufficient and appropriate equipment to carry out the operations of the pharmacy, including:** • 1 x Class 2 Balance (Electronic or Beam) • 1 x set of metric weights between 100mg to 500g • 1 x beam balance if weighing over 25g • 3 x Assorted accurate, validated glass measures to include 10ml, either 25ml or 50ml, 100ml • 1 x Mortar and Pestle • 2 x Spatulas suitable for compounding • 1 x Stirring rod • 2 x Tablet counting trays with suitable spatulas • 1 x Refrigerator for storing medicines • 1 x max/min thermometer for use in medicines refrigerator • max/min thermometer(s) for ambient temperature monitoring • 1 x an electronic dispensing system with printer producing legible and durable labels or typewriter which produces legible and durable labels • 1 x Ointment Slab **Plus any other equipment necessary to undertake any specialist compounding or manufacturing of medicines in a particular pharmacy** *MA 51(1)(e); PSA G10(a)(b)*			
C.3.4	**Are equipment and utensils designed and constructed so that they are suitable for their purpose and easy to clean, to prevent contamination of products?** *MA 51(1)(e); PSS 5.14.3; PSA G10(a)*			

SECTION C: DISPENSING, COMPOUNDING, REPACKING & BATCH PREPARATION

C.3 Pharmacy Equipment (continued)

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
C.3.5	**Is measuring, weighing, recording and control equipment calibrated and checked at defined intervals by appropriate methods? Are adequate records of such tests maintained?** *MA 51(1)(e); PSS 5.1.4,5.14.4; PSA G10(a)*			
C.3.6	**Are non-certified liquid measures validated?** *MA 51(1)(e); PSS 5.14.5*			
C.3.7	**Is designated and separate equipment used in the dispensing, compounding, repackaging and batch preparation of cytotoxic preparations?** *PSS 5.14.7*			
C.3.8	**Is dispensary equipment used for any other purpose than the preparation and dispensing of medicines?** *MA 51(1)(e); PSS 5.14.1; PSA G10(a)*			
C.3.9	**Are equipment and utensils thoroughly cleaned, maintained and adequately stored?** *MA 51(1)(e); PSS 5.14.2*			
C.3.10	**Is defective equipment clearly labelled as defective and removed from use?** *PSS 5.14.6*			

SECTION C: DISPENSING, COMPOUNDING, REPACKING & BATCH PREPARATION

C.4 Compounding Procedures

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
C.4.1	**Are there suitable SOPs for the processes of 'individual' compounding and batch compounding?** *PSS 5.15.1*			
C.4.2	**Which staff members undertake compounding? Is there an appropriate number of qualified and experienced staff? Are pharmacy graduates, pharmacy technicians and students compounding under direct personal supervision of a pharmacist?** *MR 63; PSS 5.9.2,5.15.3*			
C.4.3	**Is the compounding area maintained in a clean, uncluttered and orderly manner & are effective cleaning procedures used before commencing and at completion of product preparation?** *PSS 5.12.3,5.12.4,5.12.8,5.22.1*			

SECTION C: DISPENSING, COMPOUNDING, REPACKING & BATCH PREPARATION

C.5 Starting Materials

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
C.5.1	**Is a system set up to ensure that all materials meet the required specifications at the time of purchase and on each and every occasion the material is used?** • purchased from recognised suppliers • checked at the point of receipt • appropriate procedures or measures to assure the identity of the contents of each container • damage or contamination considered by a pharmacist and appropriate action taken *PSS 5.19*			
C.5.2	**Are starting materials received without an expiry date assigned a suitable expiry date by the pharmacist? Is the date of receipt recorded on the package if received without expiry date? Are all starting materials within the expiry date?** *PSS 5.19.6*			
C.5.3	**Are all starting materials stored under the appropriate conditions established by the manufacturer and in an orderly fashion to permit identification, batch segregation and stock rotation?** *PSS 5.10.3,5.19.7*			
C.5.4	**Is potable water to be used as a starting material of a quality appropriate for the finished product? If a water filter is used is it maintained in compliance with the manufacturer's specifications & is documentation of the filter replacements maintained?** *PSS 5.19.9,5.19.10*			

SECTION C: DISPENSING, COMPOUNDING, REPACKING & BATCH PREPARATION

C.6 Compounding Practice

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
C.6.1	**Are adequate precautions taken to prevent contamination, cross-contamination and product mix-up in all stages of preparation?** *PSS 5.22*			
C.6.2	**In the case of individual compounding where a copy of a master batch document is not used as the record, is a record kept on the premises which enables the history of the finished product to be traced, including:** • the name of the preparation • name and quantities of the ingredients used • the date of the preparation • a unique identifying number (usually the prescription number) • the batch number and expiry date of each ingredient • the expiry date of the finished product • a copy of the product label • the signature or initials of the pharmacist checking/releasing the final product *PSS 5.18.2,5.23.1,5.25.1*			
C.6.3	**Are labels that accurately describe the finished product attached to the container? Do the labels of compounded medicines contain:** • name of the pharmaceutical product • dosage form and strength where applicable • quantity in the container • instructions for use and storage • assigned batch number and expiry date • date of compounding • name of pharmacy *PSS 5.24*			
C.6.4	**For batch compounded products, are these prepared within allowable limits and documented on master batch documents that are retained for a minimum of 3 years and include:** • the name of the product • the pharmaceutical form & strength of the product • a list of ingredients together with the amount of each • an area for the batch numbers & expiry dates of ingredients • a step-by-step description of the compounding procedure • the packaging material(s) to be used • the storage conditions for the finished product • a sample of the label and any advisory/auxiliary labels • the assigned expiry date period • an area for recording the batch quantity • an area for recording the unit pack size • an area for the batch number to be assigned • an area for sign off by a pharmacist for the measuring and checking of the ingredients • an area for reconciliation of final yield and labels • an area for sign off by a pharmacist for checking/release of final product *PSS 5,5.16.4,5.17.1,5.18.1*			

SECTION C: DISPENSING, COMPOUNDING, REPACKING & BATCH PREPARATION

C.7 Repackaging & Batch Preparation

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
C.7.1	**Does the processing area only contain materials and documentation associated with the repackaging process being carried out?** *PSS 5.27.1*			
C.7.2	**Can products be identified at all times during preparation? Are labels or indications on containers and equipment clear and unambiguous?** *PSS 5.27.2*			
C.7.3	**For products regularly repackaged*, is there a master document (repackaging instruction) for each product, pack size and type including:** • **name of the product** • **dosage form and strength** • **pack size (repacked product)** • **instructions for the unpacking and repacking procedure (including any applicable in-process controls)** • **a list of the packaging materials to be used** • **storage conditions for the repacked product** • **special precautions to be observed** • **labelling text or master reference label and any advisory/auxiliary labels** • **assigned expiry date period (repacked product)** • **an area for the original manufacturer's batch number and expiry date** • **an area for the in-house batch number and expiry date to be assigned** • **an area for sign off by a pharmacist for checking the label** • **an area for recording the product and packaging material quantities issued** • **an area for recording the product and packaging material quantities used or returned** • **an area for reconciliations of final yield, packaging materials and labels** • **an area for sign off by the pharmacist for checking/release of the final product** *PSS 5.28.1* ***Note.** Strip packaged medicine that retains labelling, batch number and expiry date may be repackaged prior to dispensing without necessarily requiring documentation, provided that a robust checking procedure is followed.* *PSS Repackaging of Medicines Principle*			

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
C.7.4	**Are appropriate records for repackaging of medicines maintained, including:** • date of processing • name of the qualified staff member performing the operation • name/strength/dose form and material names to be recorded • quantities of all printed packaging materials, containers and bulk product, issues, used, destroyed or returned to stock • quantity of repackaged units prepared • a reconciliation for all components involved in the packaging procedure • batch number and expiry date of original product • assigned in-house batch number and expiry date of the repackaged product • a sample label and any auxiliary labels • the signature or initials of the pharmacist checking/releasing the finished product *PSS 5.29.1*			
C.7.5	**Are packaging materials suitable for the products they will contain?** *MR 32,33; PSS 5.30*			
C.7.6	**Does the pharmacist assign an appropriate expiry date with regards to the expected storage conditions?** *PSS 5.32.1*			
C.7.7	**Do labels for repackaged medicines contain the following:** • name of the product • dosage form and strength where applicable • pack size • assigned batch number and expiry date • date of repackaging • name of the pharmacy *PSS 5.32.2,5.33.1*			
C.7.8	**Is there a defined step where the finished product is compared by the pharmacist taking responsibility for quality with the product specifications and released or rejected?** *PSS 5.34.1*			
C.7.9	**Are rejected materials and products identified and segregated?** *PSS 5.35.1*			

SECTION D: MANAGEMENT OF PHARMACEUTICALS

D.1 OTC Sales & Drugs of Misuse

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
D.1.1	**Are OTC products with the potential for misuse appropriately stored/displayed in the pharmacy?** • **codeine-containing preparations** • **pseudoephedrine-containing preparations** • **opioids** • **sedating antihistamines, sleeping aids, travel sickness medication** • **laxatives which may be abused** *CoE 3.16,3.18; PCNZ Guidance: Advertising to the Consumer and Promotion of Products of Potential Misuse*			
D.1.2	**Are staff aware of strategies for dealing with OTC sales of medicines where misuse is suspected?** *CoE 3.15*			
D.1.3	**Are medicines repacked for OTC sale appropriately labelled, including patient name?** *MR 23*			
D.1.4	**Are sales of OTC medicines appropriately supervised by a pharmacist?** *MA 42A; CoE 3.18*			

SECTION D: MANAGEMENT OF PHARMACEUTICALS

D.2 Restricted Medicines

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
D.2.1	**Are restricted medicines stored or displayed for sale in a position that does not allow young children or unauthorised people to have ready access?** *MA 47(1)(b)*			
D.2.2	**Does a pharmacist provide appropriate advice in a private and confidential manner & sell restricted medicines?** *MA 18(1)(b); PSS 3.3.1*			
D.2.3	**Do the records of sales comply with legal requirements?** • **date of sale** • **buyers name and address** • **name & quantity of medicine sold** • **name of pharmacist taking responsibility for the sale** *MR 54A,55; HIPC Rule (1)a*			
D.2.4	**If using a physical register, how are past entries kept confidential when it is in use?** *HIPC Rule 4,5*			
D.2.5	**If electronic, are the records retrievable for audit?** *MR 54A (2)(b)*			
D.2.6	**Are sales of ECP made by an accredited pharmacist? Are records of consultations and dispensings retained? How are dispensings labelled?** *PCNZ Best Practice Guidelines for the Supply by Pharmacists of the Emergency Contraceptive Pill January 2008*			

SECTION D: MANAGEMENT OF PHARMACEUTICALS

D.3 Pharmacy Stock

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
D.3.1	**Is there an appropriate SOP for the ordering and checking of incoming medicines?** *PSS 2.3.3*			
D.3.2	**Are storage areas (including dispensary, retail and other storage areas) for medicines satisfactory and in a clean and tidy condition?** *MA 47; MR 29,32*			
D.3.3	**Do the storage area(s) provide appropriate & sufficient protection from:** • **direct sunlight / light where applicable** • **moisture** • **insects, animals, vermin** *MA 47; MR 29,32; PSA G10(a)*			
D.3.4	**Are ambient room temperatures monitored and documented, including monitoring when the pharmacy is closed? Is there an appropriate SOP, including actions to take if the temperature exceeds 25°C?** *PSS 5.13.2; PSA G10(a)*			
D.3.5	**Are pharmaceuticals suitable for dispensing?** • **obtained from a licensed wholesaler?** • **packaging not crushed/wet/damaged** • **stock stored in original containers? (If not, how is it stored and labelled?) (e.g. cut strips?)** • **returned stock recycled or reused?** *MR 32,34,35*			
D.3.6	**What are the systems for checking expiry dates of stock & is all stock within expiry date? (including controlled drugs, refrigerated & retail pharmaceuticals)** *PSS 5.1.2*			
D.3.7	**Are all hazardous substances correctly labelled to allow for easy identification and safe use in line with the Hazardous Substances (Identification) Regulations and local authority requirements?** *PSS 4.1.4*			
D.3.8	**Does the pharmacy follow an appropriate documented procedure for handling medicine recalls? Are records of recalls retained in the pharmacy?** *PSS 5.2.3(i)*			

SECTION D: MANAGEMENT OF PHARMACEUTICALS

D.4 Medicines Requiring Refrigeration

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
D.4.1	**Is there an appropriate SOP for fridge temperature monitoring and cleaning? Does this include guidance on appropriate corrective measures when medicines requiring refrigeration have not been stored within the range 2 – 8°C?** *PSS 5.13.4*			
D.4.2	**Is the fridge suitable for the storage of medicines?** • **clean** • **frost-free** • **foodstuffs stored appropriately to prevent cross-contamination** *MA 47; MR 32,36; PSS 5.13.3*			
D.4.3	**Is the refrigerator maximum/minimum temperature appropriately and regularly monitored & documented to ensure maintenance within the range 2-8°C? Is there evidence of appropriate action taken if the temperatures have gone out of range?** *PSS 5.13.1,5.13.4*			
D.4.4	**Is the maximum-minimum thermometer (including electronic devices eg, datalogger) regularly calibrated & validated?** *PSS 5.14.4*			

SECTION D: MANAGEMENT OF PHARMACEUTICALS

D.5 Waste Disposal

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
D.5.1	**Is there an appropriate SOP for safe and appropriate storage and disposal of waste, infectious and hazardous substances?** *PSS 4.1.1*			
D.5.2	**Is there a clearly labelled/ designated area for quarantine of rejected/returned medicines?** *PSS 5.26*			
D.5.3	**Is pharmacy waste disposed of appropriately?** • **general waste** • **confidential patient information** • **pharmaceuticals** • **cytotoxics** • **infectious/ hazardous substances** • **sharps** • **using protective equipment and clothing appropriate to the risks involved** *MR 29(c); PSS 4.1,4.2.4,4.2.5,5.11.1; CoE 3.22*			

SECTION E: RISK MANAGEMENT

E.1 Quality Improvement Systems

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
E.1.1	**Does the organisation have approved policies and SOPs that are aligned with current good practice and service delivery, meeting the requirements of legislation, and reviewed at appropriate regular intervals? Are these readily accessible by staff?** *PSS 2.3.3,3.8.2,5.10.3; PSA G3*			
E.1.2	**Do service providers have job descriptions and receive an orientation/induction programme (including locums) that covers the essential components of the service provided?** *PSS 2.5.1,2.5.4*			
E.1.3	**How are staff involved in ongoing training and development? Is this training documented?** *PSS 2.5.5,4.4.1,5.10.2,5.10.4; PSA G9(c)*			
E.1.4	**Do service providers receive appropriate information, training and equipment to respond to identified emergency and security conditions (including fire safety, emergency procedures and armed hold-ups)? Is this documented?** *PSS 2.5.5,4.4.1*			
E.1.5	**Are service providers able to provide a level of first aid and emergency treatment appropriate for the degree of risk associated with the provision of the service?** *PSS 4.4.2; PSA G5.6*			
E.1.6	**Does the pharmacy follow an appropriate SOP for infection control including reference to:** • **cleaning schedules/procedures** • **waste management (eg, gloves, cleaning bins)** • **hand washing/drying (eg, where, when, how)** • **needle stick injury prevention measures and procedures for action in case of needle stick injury** • **infectious disease policy** • **wound management** • **incident reporting** • **review plan for incidents** *MR 26,27; PSA G5.3*			

SECTION E: RISK MANAGEMENT

E.2 Complaints Management

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
E.2.1	**Is there an easily accessible, responsive and fair complaints process documented in an SOP that includes reference to:** • **the Code of Health and Disability Services Consumers' Rights** • **how consumers are made aware of the procedure for making a complaint** • **an appropriate form to record complaints** • **how these records are stored (e.g, folder)** • **who is the responsible person in the pharmacy** • **an appropriate review process and feedback to staff** *HDC Right 10; PSS 1.11.1; PSA G6.1(b),G6.3*			
E.2.2	**Is information about a consumer's right to complain and the complaints process available for consumers?** *PSS 1.11.2; PSA 6.1(a)*			
E.2.3	**Is an up-to-date complaints register maintained that includes all complaints, dates, and actions taken?** *PSS 1.11.3*			

SECTION E: RISK MANAGEMENT

E.3 Prescription Interventions

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
E.3.1	**Is there a SOP for handling and documenting prescription interventions?** *PSS 1.7.1,3.5.1,3.8.1; PSA G5.4, Schedule C1 Base Pharmacy Services 7.1(d); CoE 3.12,3.13*			
E.3.2	**How are prescription interventions recorded?** *PSA G5.4*			
E.3.3	**Are they recorded consistently? Could the system be used to retrieve a specific intervention in the case of a complaint or inquiry?** *PSS 3.6.2; PSA G5.4*			

SECTION E: RISK MANAGEMENT

E.4 Pharmacy Incidents (Adverse Events)

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
E.4.1	**Does the pharmacy follow appropriate SOPs for managing, documenting and reviewing pharmacy incidents (including but not limited to emergency and security conditions & dispensing incidents)?** **Do the SOPs include reference to:** • **a definition of what constitutes an incident** • **guidance for managing an incident (including who is responsible)** • **who should be contacted on identification of the incident** • **a description of how incidents are documented & a sample of the incident form(s) used** • **guidance for review of the incident (including but not limited to implementation of corrective actions, debriefing & counselling)** • **evaluation of the incident to ensure the corrective actions have been implemented and , with the aim of preventing future incidents** • **a system for review of incidents** *PSS 2.3.1,2.3.5,2.3.7,2.3.8,2.4,3.8.1,3.6.1,3.6.2; PSA G.5.4; CoE 3.12,3.13*			
E.4.2	**Are dispensing incidents (near-miss events & dispensing errors) consistently & appropriately documented? Are appropriate corrective actions implemented to prevent future dispensing incidents?** *PSS 2.3.1,2.3.5,2.3.7,2.3.8,2.4,3.6.1,3.6.2; PSA G.5.4*			

SECTION E: RISK MANAGEMENT

E.5 Security

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
E.5.1	**Is there sufficient security to ensure all medicines remain secure?** • **when the pharmacy is open?** (eg, shoplifting, uninvited access to dispensary) • **when the pharmacy is closed?** (including pharmacy within other premises) • **in the storage areas?** • **is the location of the alarm sensors suitable?** (eg, covers dispensary and area where safe is located) *MA 42B; PSS 4.4.1,4.4.4*			

SECTION F: FACILITIES

F.1 Dispensary Facilities

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
F.1.1	**Is the dispensary a distinct identifiable area, which discourages uninvited access?** *PSS 5.12.1,5.12.10*			
F.1.2	**Does the size and layout of the dispensary allow for efficient workflow and direct staff supervision?** *PSS 5.12.2*			
F.1.3	**Are any non-dispensing activities undertaken in the dispensary that compromise the compounding or dispensing operations performed or the quality of final products?** *PSS 5.12.2,5.12.8*			
F.1.4	**Where a dispensing area is used for more than one activity, do these activities impose on each other?** *PSS 5.12.2*			
F.1.5	**Is the dispensary maintained in an uncluttered and orderly manner, free of any material that is not required for dispensing?** *PSS 5.12.8*			

SECTION F: FACILITIES

F.2 Pharmacy Premises

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
F.2.1	**Does the physical environment minimise the risk of harm (hazards?), aid independence, and appropriately meet the needs of service providers and the consumers?** *PSS 4.2.4; PSA G10*			
F.2.2	**Are areas used by consumers and service providers ventilated, smokefree, lit and heated/cooled appropriately?** *MR 29(b); PSS 4.5; PSA G5.2*			
F.2.3	**Are the premises in a suitable condition for use as a pharmacy, including but not limited to the following areas being constructed of impervious and washable materials that are clean, hygienic and maintained in a good state of repair:** • **smooth working surfaces** • **shelves, cupboards & drawers (internal & external)** • **sinks (including those used for hand washing)** • **floor(s) in the dispensing area(s)** • **smooth floor in the compounding area(s)** • **ceiling** • **walls (including junction with other surfaces)** • **toilet facilities** *MR 29; PSS 4.2.5;5.12.12*			
F.2.4	**Are schedules for cleaning dispensing and compounding areas maintained?** *MR 29(d)*			
F.2.5	**Is there a separate staff rest and refreshment room in the pharmacy?** • **If no room: Are there designated areas for eating, drinking and other non-dispensing/compounding practices?** • **Is this area/room kept in a clean and tidy state?**			
F.2.6	**Are accessible toilets conveniently located?** • **in adequate numbers** • **not opening directly into dispensing/compounding areas** *MR 29; PSS 4.3.1,4.3.3*			
F.2.7	**Are there adequate hand washing facilities:** • **located in or immediately adjacent to all toilet areas** • **located in proximity to each service area** **Is each hand washing facility provided with an adequate supply of:** • **cold water & hot water at a safe and appropriate temperature to minimise the risk of harm** • **soap or other detergent** • **disposable towels or other suitable methods of hand drying** *MR 29(i); PSS 4.3.1,4.3.2,4.3.3*			

SECTION G: SERVICES

G.1 Service Information

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
G.1.1	**Is appropriately written information available for Eligible People and other interested parties which describes:** • **the services offered by the pharmacy** • **the location of these services** • **the hours of access** • **service users' rights and responsibilities** • **any other information to enable Eligible People to access the services** *PSS 3.1.3; PSA G7.2*			
G.1.2	**Is there a notice prominently displayed on the outer door or window specifying:** • **when the Pharmacy is closed** • **how Eligible People can obtain essential pharmaceuticals during the period when the pharmacy is closed** *PSA Schedule C1 6.2(d)*			

SECTION G: SERVICES

G.2 Needle Syringe Exchange Programme

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
G.2.1	**Is written information available for consumers about the needle syringe exchange scheme, and a list of providers in the local area?** *PSA Schedule C1 Base Pharmacy Services 7.1(b)(vi)*			
G.2.2	**Is the pharmacy involved with the Needle Syringe Exchange Programme, or sale of needles?** **If YES, is there an SOP including reference to:** • **dealing with clients** • **preventing and managing needle stick injuries** • **safe disposal of used needles** *PSA G5.3(a)*			

SECTION G: SERVICES

G.3 Online Pharmacy Services

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
G.3.1	**How does the provider ensure that the standard of advice and service available by electronic media is of the same level as that received by a consumer consulting with a pharmacist face-to-face?** *PSS 3.9.1*			
G.3.2	**Does the promotion and supply of medicines over the internet comply with the statement set by the Pharmacy Council of New Zealand on the *Promotion and supply of medicines over the internet*?** *PSS 3.9.2; PCNZ statement*			
G.3.3	**How do pharmacists comply with legal requirements when giving advice or selling medicines via online contact?** *PSS 3.9.3*			
G.3.4	**How do pharmacists comply with professional and ethical obligations when providing online pharmacy services?** *PSS 3.9.4*			
G.3.5	**Can the charge pharmacist demonstrate responsibility for the form and content of all information made available on the website?** *MA 57, 58, 59; PSS 3.9.5*			

SECTION G: SERVICES

G.4 Remote Pharmacy Services

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
G.4.1	**Does the pharmacy service any prescription depots? If YES, how does the pharmacy ensure the depot is appropriately authorised (Authority to Possess Prescribed Medicines)?** *MA 43*			
G.4.2	**Are there appropriate SOPs for providing services to the depot(s)?** *PSS 2.3.3*			
G.4.3	**How are prescriptions presented to the pharmacy?** • **from legitimate source?** • **how is the original obtained?** *MA 18(2); PSS 5.2.3; CoE 2.6*			
G.4.4	**How are medicines delivered to the depot?** • **protect consumer confidentiality?** • **does the pharmacy maintain a record of delivery including dispatch date, method of dispatch and address delivered to?** *MA 47; CoE 1.8,3.5*			
G.4.5	**How does the pharmacy ensure medicines are given to the correct person?** • **does the depot maintain records of medicine collection?** • **does the pharmacy receive a copy of these records?** *MA 47; PSS 5.2.3*			
G.4.6	**What is the process for uncollected medicines?** • **when returned to the pharmacy?** • **delivery system?** • **documentation?**			
G.4.7	**How does pharmacy provide access to counselling and advice?** *PSS 1.8; CoE 1.2,1.11,2.7*			
G.4.8	**How does the pharmacy provide ongoing support and training to staff at the depot?** *PSS 2.5*			

SECTION H: COMPLIANCE PACKAGING

H.1 Compliance Packaging Procedures

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
H.1.1	**Is there an appropriate SOP for compliance packaging which includes:** • **a description of the area used for compliance packaging** • **pharmacist supervision and signoff at each stage of the operation (how is this recorded?)** • **checking and packing procedures that will minimise the possibility of errors** • **a system to identify non-compliant patients** • **provision to supply feedback to prescribers** *PSS 5.4*			
H.1.2	**Are qualified staff involved in the compliance, dose and unit dose packing procedure trained and competent in the procedure? Is training documented?** *PSS 5.36.1,5.9*			
H.1.3	**Is a protocol in place describing the frequency for cleaning/disposing of the equipment used to place the medication into the unit dose pack?** *PSS 5.36.4,5.37.3*			
H.1.4	**Is documentation related to the prescription and compliance packaging completed before the packing operation is undertaken (eg, medication chart (if used))?** *PSS 5.38.1*			
H.1.5	**Are medication charts kept for each patient?** • **Are they checked and signed by the pharmacist?** • **How are medication changes handled?** • **How are records maintained of these changes?** • **Are charts checked against each pack?**			

SECTION H: COMPLIANCE PACKAGING

H.2 Compliance Packaging Area

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
H.2.1	**Is the designated area of a sufficient size to allow for separation of packing, checking and storage of finished packs?** *PSS 5.37.1*			
H.2.2	**Is the area used thoroughly cleaned before and after the operation?** *PSS 5.37.3*			
H.2.3	**Is only the equipment necessary for the repackaging process kept in this area while packs are being prepared or checked?** *PSS 5.37.4*			
H.2.4	**Are packs awaiting delivery, returned packs and packs awaiting change stored in areas clearly labelled and distinct from one another to ensure there is no ambiguity over the status of a pack?** *PSS 5.37.2*			

SECTION H: COMPLIANCE PACKAGING

H.3 De-blistering of Medicines

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
H.3.1	**Is a batch record kept for each medicine that is removed from its original blister packaging for later use in compliance, dose, or unit dose packaging?** *PSS 5.39.1*			
H.3.2	**Do the batch records include the:** • date of de-blistering • name, strength and dosage form of the medicine • original batch number and expiry date of the medicine • identity of the person performing the procedure • identity of the pharmacist checking the end product • new assigned expiry date for the medicine in that container by the pharmacist *PSS 5.39.2*			
H.3.3	**Do labels of de-blistered medicines contain the following:** • name, strength and dosage form of the medicine • date the medicine was de-blistered and packed into the container • original batch number of the medicine • assigned expiry date *PSS 5.39.3*			
H.3.4	**Is a check made of the de-blistered medicines in the repacked container to ensure integrity of the medicines is maintained?** *PSS 5.39.4*			
H.3.5	**Does de-blistering of medicines only involve sufficient quantity for two week's use at a time?** *PSS 5.39.5*			
H.3.6	**Is only one medicine de-blistered at a time with the process finished and checked off by the pharmacist, before another medicine de-blistering process begins?** *PSS 5.36.1*			

SECTION H: COMPLIANCE PACKAGING

H.4 Compliance Packaging Practice

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
H.4.1	**Are only those medicines suitable for compliance, dose, or unit dose packing put into packs? Are procedures in place to manage medicines not suitable for compliance, dose, or unit dose packs?** *MR 32; PSS 5.36.2*			
H.4.2	**To reduce the risk of contamination does the person packing the medication into the compliance, dose, or unit dose pack ensure there is no direct contact with the medication? For example, handlers use gloves or forceps.** *PSS 5.36.3*			
H.4.3	**Are packs checked and sealed as soon as practicable after filling, and packs sealed on the day of preparation?** *MR 32; PSS 5.36.5,5.36.6*			
H.4.4	**Are packs labelled with the following details:** • **name of the consumer** • **name and address of the pharmacy** • **date of preparation of the pack** • **strength and name of all medications in the pack** • **prescription/reference number** • **directions for use; dose and frequency of dose of medication in the pack written in English** • **appropriate cautionary and advisory labels** *MR 17,23; PSS 5.40.1*			
H.4.5	**Where a pack has perforations to enable separation of the individual dose units for each dose period, does the labelling on each individual dose shall have:** • **consumer's name** • **name and strength of each medication contained in the dose unit** • **quantity of each medicine** • **dose time and day** *PSS 5.40.2*			
H.4.6	**Is a final check made against the appropriate authorisation following the normal checking procedure for dispensed medicines?** *PSS 5.41.1*			
H.4.7	**Is this final check recorded both on the pack and on a document that contains the pharmacist identity and date, which remains on the pharmacy premises?** *PSS 5.38.2;5.41.2*			
H.4.8	**Are compliance packs rejected at the final check quarantined until corrected and rechecked, or appropriately disposed of?** *PSS 5.41.3*			

SECTION H: COMPLIANCE PACKAGING

H.5 Care Facilities/ Institutions

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
H.5.1	**Does the Pharmacy have an appropriate SOP for the supply of pharmaceuticals or services to each facility and is this followed? Including:** • delivery (when, how and quantity supplied) • drug information service • emergency medical supplies • 'prn' medicines (contained in blister packaging where possible) • discontinued / returned medicines (including CDs) • maintenance of medication profiles • special storage items including: ▪ refrigerated items ▪ controlled drugs (appropriate packaging?) • liaison with facility staff and prescriber i.e. records of clinical interventions, delivery of medication, regular visits to the facility **For certified hospital institutions:** • how is imprest stock checked? • stock rotation? *PSS 3.2.3,3.5.2,5.2.1; PSA 7.1(h),G8; SMM*			
H.5.2	**How are pharmaceutical products requested by the facility?** • are suitably authorised written orders received? • written orders received at least every 3 months and when changes occur? • Including requests for 'prn' medication? • if changes occur, how is the accuracy of patient records maintained? *PSS 2.7.5,3.2.4,5.38.1; SMM*			
H.5.3	**What records are held in the pharmacy for each patient in the facility receiving medication?** • How are they filed? • How are they verified? *PSS 2.7.1,2.7.2,2.7.4,2.7.7,2.7.9; SMM*			

SECTION I: AUTOMATED PACKING & DISPENSING

I.1 Automated Devices

Auditor note: *If automated packing & dispensing services are provided, section H must also be audited.*

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
I.1.1	**Are all processes involved clearly defined, recorded, reviewed and known to be capable of consistently producing accurately dispensed packed medicines?** *PSS 5.42.1*			
I.1.2	**Are critical steps of the process (including software systems) validated?** *PSS 5.42.2*			
I.1.3	**At every stage of processing are products and materials protected from microbial and other contamination?** *MR 27,29(d),32(1),34; PSS 5.42.3*			
I.1.4	**Is thorough checking of the end product undertaken by a pharmacist before release of the product for supply?** *PSS 5.42.4*			
I.1.5	**Is adequate and suitable space available for the automated device to operate?** *MA 51(1)(e); PSS 5.42.5*			
I.1.6	**Are qualified staff performing the entry of the profile (cycle date, medicines to be packed, frequency, and dose, if signing sheets are required)?** *PSS 5.42.6*			
I.1.7	**Is the automated device calibrated according to the manufacturer's specifications?** *MA 51(1)(e); PSS 5.42.7*			

SECTION I: AUTOMATED PACKING & DISPENSING

I.2 Staff

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
I.2.1	**Does the pharmacy manager ensure that all staff involved in the automated packaging process are appropriately qualified as required by the Medicines Regulations and have received appropriate training?** *MR 42(1), 42(1A); PSS 5.43.1*			
I.2.2	**Has the pharmacy manager ensured that procedures related to health, hygiene practices and clothing have been established?** *PSS 5.43.2*			

SECTION I: AUTOMATED PACKING & DISPENSING

I.3 Filling the Reservoirs/Canisters with Medicines

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
I.3.1	**Is the system for filling reservoirs/canisters with medicines validated?** *PSS 5.44.1*			
I.3.2	**Is there a system for identifying medicines not suitable for processing through the automated device?** *PSS 5.44.2*			
I.3.3	**Is a record made of the:** • **batch number of the medicine** • **expiry date of the medicine** • **identification of the person filling the canister** • **date of filling** *PSS 5.44.3*			
I.3.4	**Before an exceptions tray is loaded into the automated device for packing, are the medicines checked for accuracy?** *PSS 5.44.4*			
I.3.5	**Are reservoirs/canisters containing controlled drugs (eg, codeine) appropriately handled?** • **removed from device at end of process** • **stored in controlled drug safe when not in immediate use**			

SECTION I: AUTOMATED PACKING & DISPENSING

I.4 Cleaning the Automated Device

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
I.4.1	**Are there SOPs and schedules available for cleaning all parts of the automated device?** *PSS 5.46.1*			
I.4.2	**Are documented records of cleaning the device maintained including:** • **identity of the person** • **date and time** *PSS 5.46.2*			

SECTION I: AUTOMATED PACKING & DISPENSING

I.5 Checking the Finished Product

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
I.5.1	**Is a check made against the appropriate authorisation and does it follow the normal checking procedure for dispensed medicines within the pharmacy?** *PSS 5.47.1*			
I.5.2	**Is the checking process documented and retained on the pharmacy premises?** *PSS 5.47.2*			
I.5.3	**Is each medicine container appropriately labelled including:** • **name of the consumer** • **name and address of the pharmacy** • **date of preparation of the pack** • **strength and name of all medications in the pack** • **prescription/reference number** • **directions for use; dose and frequency of dose of medication in the pack written in English** • **cautionary and advisory labels** *MR 12,17,18,23; PSS 5.47.3*			
I.5.4	**If medicines are placed in individual sachets:** • **does the labelling of each individual sachet include:** o **consumer's name** o **name and strength of each medication contained in the dose unit** o **quantity of each medicine** o **dose time and day** • **Is there a 'header' label for the entire dose pack, and is this labelled in accordance with the requirements of audit tool criterion I.5.3?** *PSS 5.40.2,5.47.4*			
I.5.5	**Is there an SOP for handling rejected packs, following GMP principles? Is this followed?** *PSS 5.47.5*			

SECTION J: CLOZAPINE DISPENSING

J.1 Clozapine Dispensing

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
J.1.1	**Is there an appropriate SOP for the dispensing of clozapine? Does this include reference to:** • **checking the patient is registered with the appropriate pharmaceutical company before supplying medication for the first time** • **maintaining individual records for each client, which are kept secure and confidential** • **ensuring a satisfactory blood test result is available before dispensing each supply** • **the action to be taken if blood results are outside specified range** • **supplying the correct amount of medication according to when the full blood count was taken and when the client collects the medication** • **the action to be taken if problems arise (i.e. blood levels out of range, late, patient not collecting medication)** • **maintaining a list of up to date contact telephone numbers for each patient** *PSS 2.7.1,2.7.2,2.7.9,3.3.1; PSA Schedule C2 Protocol for the Dispensing of Clozapine by Community Pharmacies*			
J.1.2	**Does the pharmacy follow the SOP for clozapine dispensing?** *PSS 3.8.1,3.8.2; PSA Schedule C1 Pharmacy Clozapine Services 6.1*			

SECTION K: OPIOID SUBSTITUTION TREATMENT

K.1 Methadone Dispensing Procedures

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
K.1.1	**Is there an appropriate SOP describing the process for methadone dispensing and recording, including:** • the dispensing process • strength of methadone used appropriate for doses dispensed • how liaison with the clinic is maintained • where 'consume on premises' doses are given out • record keeping • regular stocktake of methadone solutions *PSA G6.5, G8, Schedule C1 Pharmacy Methadone Services for Opioid Dependence 6.1; OST 11.10*			
K.1.2	**Are all variations to doses and changes to regimes authorised by the prescriber or key worker?** • are these authorisations retained (4 years)? • filed appropriately? *MoDR 24(1); OST 11.8*			
K.1.3	**Are up to date and accurate records kept for each patient?** *PSA G13*			

SECTION K: OPIOID SUBSTITUTION TREATMENT

K.2 Methadone Dispensing Practice

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
K.2.1	**Is a valid prescription present for each dispensing (i.e. no anticipated prescriptions?) Are dispensed prescriptions appropriately annotated?** *MoDR 24(1),29; OST 11.1,11.3,11.8*			
K.2.2	**Is the measuring equipment (burette/syringe/measure):** • appropriate and accurate • regularly calibrated • appropriately cleaned after each use *OST 11.3, 11.4*			
K.2.3	**Are methadone takeaway doses dispensed in clean, new containers with child resistant closures (CRCs)?** *MR 35; OST 11.6*			
K.2.4	**How is the collection of takeaway doses recorded in the pharmacy?**			

SECTION K: OPIOID SUBSTITUTION TREATMENT

K.2 Methadone Dispensing Practice (continued)

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
K.2.5	**Do the labels meet requirements for:** • **'Consume on premise' doses (if prepared in advance)** • **takeaway doses** *MA 23; OST 11.3,11.6*			
K.2.6	**Are 'consume on premise' doses provided appropriately?** • **in an appropriate area within the pharmacy** • **identity of client checked** • **using disposable cups & water appropriately provided** • **supervised and observed by a pharmacist in a private and confidential manner** *OST 11.3,11.4*			
K.2.7	**Is waste disposed of appropriately?** • **'consume on premise' doses in a lined, covered rubbish bin, and where possible a biohazard container used?** • **confidential information?** *PSA G5.3(a),G6.5(a); OST 11.4*			
K.2.8	**Is storage of methadone appropriate for:** • **'Consume on premise' & takeaway doses** • **methadone stock bottles** • **measuring equipment (burette/syringe/measure)** • **dispensed methadone when the pharmacy is unattended** *MR 28; OST 11.3*			

SECTION K: OPIOID SUBSTITUTION TREATMENT

K.3 Methadone Recording

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
K.3.1	**Does the pharmacy use an approved methadone recording system? Is the recording system clear, easy to follow, and well maintained?** *MoDR 37,39,40; OST 4.11*			
K.3.2	**If methadone recording sheets are used:** • **total(s) transferred to the controlled drug register daily?** • **retained on the premise for 4 years?** *MoDR 39,42(1)*			
K.3.3	**Are stock takes sufficient to ensure an accurate balance can be maintained?** • **does this include explanations of stock adjustments?** *MoDR 43*			

SECTION L: ASEPTIC DISPENSING OF STERILE PRODUCTS

L.1 Risk Management

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
L.1.1	**Are SOPs maintained to control the aseptic dispensing process including:** • all key elements and manipulative steps to facilitate consistent production of a product of the required quality • following established and validated methods • clear, standardised and detailed documents • regularly reviewed (at intervals of not more than 2 years) • superseded documents clearly identified as such *PSS 6.7*			
L.1.2	**Is a risk assessment conducted before any aseptic dispensing is undertaken?** *PSS 6.1*			
L.1.3	**Is regular monitoring of the process and finished products undertaken, including microbiological analysis of finished products as appropriate?** *PSS 6.12*			
L.1.4	**Is there a system for capturing, investigating and documenting errors, near-misses, defects, complaints and recalls?** • written procedures documenting incidents such as errors, near-misses, defects, complaints, or other signals indicating quality problems • subsequent investigation of these incidents and any remedial actions taken documented • process available to track and recall any dispensed product *PSS 6.13*			

SECTION L: ASEPTIC DISPENSING OF STERILE PRODUCTS

L.2 Staff & Training

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
L.2.1	**Are there sufficiently competent staff to carry out all the tasks required for aseptic dispensing?** *PSS 6.2.1; CoE 3.21*			
L.2.2	**Before undertaking aseptic dispensing have all staff received training in the appropriate skills and knowledge including:** • An appropriate knowledge of quality assurance processes • Competence in the necessary manipulative skills • Knowledge of pharmaceutical microbiology • A working knowledge of the products and services provided **Is this training documented?** *PSS 6.2.2,6.2.3*			
L.2.4	**Is the competence of staff assessed annually and revision or retraining provided if necessary (including for example change of process and/or equipment)?** *PSS 6.2.4*			
L.2.5	**Does a designated trainer or an accredited provider undertake assessment of the competence of the staff? Is operator training and performance monitored (peer observation or an annual broth validation)?** *PSS 6.2.5,6.12.3*			
L.2.6	**Do staff who have been absent from the aseptic dispensing process for 6 months or more have their technique re-evaluated before commencing aseptic dispensing?** *PSS 6.2.6*			
L.2.7	**How are infections and skin lesions assessed to determine whether the operator can safely dispense aseptic products?** *PSS 6.2.7*			

SECTION L: ASEPTIC DISPENSING OF STERILE PRODUCTS

L.3 Facilities & Equipment

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
L.3.1	**Is all aseptic dispensing carried out in a still air box (SAB), isolator, laminar flow unit, or other validated device?** *PSS 6.3.1*			
L.3.2	**Is the device located in a dedicated area which is separate from the main pharmacy dispensing areas and areas of high traffic? Is it separate from such environments as wet areas, air flow, carpets or storage areas?** *PSS 6.3.2*			
L.3.3	**Are only staff who are actively involved in the aseptic dispensing process allowed access to the dedicated area during aseptic dispensing?** *PSS 6.3.3*			
L.3.4	**Does the dedicated area have sufficient space to allow the decontamination and transfer of equipment into the device?** *PSS 6.3.4*			
L.3.5	**Is the device:** · **able to be easily cleaned and disinfected (smooth and impervious surfaces)?** · **cleaned regularly even when not in frequent use?** · **closed when not in use?** *PSS 6.3.5,6.3.6,6.3.7*			
L.3.6	**Is the isolator, laminar flow unit or other validated device used in accordance with any operating instructions?** *PSS 6.3.8*			

SECTION L: ASEPTIC DISPENSING OF STERILE PRODUCTS

L.4 Clothing

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
L.4.1	**Do staff who are actively involved in the aseptic dispensing process wear appropriate clothing to minimise the risks of contamination?** • head coverings (to totally cover the hair) and masks • a non-shedding gown or apron worn to cover the critical area of the operator's body • no garments that create particles (eg, woollen jumpers or jerseys) • all visible jewellery removed (eg, wrist watches, bracelets and rings) • no cosmetics, nail polish, false nails • new head covering, mask, gown and gloves used for each session *PSS 6.4*			
L.4.2	**Is appropriate hand hygiene followed?** • wash hands, nails and arms to the elbows using an anti-bacterial scrub and water for a minimum of 2 minutes • dry hands and forearms using a non-linting cloth *PSS 6.4.7*			
L.4.3	**Are powder-free gloves worn that have been disinfected prior to use or are sterile?** *PSS 6.4.3*			
L.4.4	**Are gloves:** • disinfected when removed from the work device or otherwise contaminated? • inspected for punctures or tears and replaced immediately if punctured or torn? **Are products that have been compounded during the time when gloves could have been punctured discarded?** *PSS 6.4.8,6.4.9*			

SECTION L: ASEPTIC DISPENSING OF STERILE PRODUCTS

L.5 Aseptic Process

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
L.5.1	**Is the device cleaned before the commencement of any aseptic dispensing session?** **(a) Still air box (SAB)** • Spray all the inside surfaces and the lid with 70% alcohol • Use wipes impregnated with 70% alcohol to disinfect each surface of the designated workstation. Use long, overlapping strokes in the following order: base, ceiling, back, sides, front, base and lid. • Replace the lid and let the alcohol dry for 2 minutes **(b) Other devices** • According to validated standard operating procedures *PSS 6.5.1, 6.5.2*			
L.5.2	**Are batch records sufficient?** • to allow traceability of starting materials and components • to establish an audit trail for the completed product • signed/initialled by the person who checked the calculations *PSS 6.6.2, 6.6.4*			
L.5.3	**Are appropriate labels that accurately describe the aseptically dispensed product attached to the containers immediately follow filling and closing of the syringe in the aseptic procedure & include:** • ingredients • total volume • infusion period • storage requirements • expiry date/time • batch number or other traceable identification • date of manufacture • name of the patient • name and address of the pharmacy • prescriber instructions *PSS 6.10.1, 6.10.2*			
L.5.4	**Does the packaging ensure the integrity of the product and maintain asepsis?** • protection from gross contamination • protection from light (where necessary) • syringe(s) appropriately packaged for storage and transport *PSS 6.11*			
L.5.5	**Is there a defined step where the finished product is visually examined, compared with its specifications and released or rejected?** *PSS 6.8*			
L.5.6	**Is the device workstation disinfected at the end of the dispensing process?** *PSS 6.5.4*			

SECTION L: ASEPTIC DISPENSING OF STERILE PRODUCTS

L.5 Aseptic Process (continued)

Criteria		Level of attainment	Level of risk	Audit Findings / Notes
L.5.7	**Are the syringe(s) packaged to prevent the relative movement of components such as the syringe barrel or syringe caps becoming dislodged during transport and storage?** *PSS 6.11.2*			
L.5.8	**Are products stored under refrigeration, normally 2-8°C, unless it would be detrimental to the product to do so?** *PSS 6.9.1*			
L.5.9	**Are expiry dates assigned to all aseptic products according to known standards or literature?** *PSS 6.9.2*			
L.5.10	**Is documentation relating to batch preparation and repacking retained for a minimum of 3 years after the expiry date of the preparation?** *PSS 6.6.3*			