Pharmacy Quality Audit 4

Integrated requirements of the Ministry of Health and District Health Boards

Audit tool version 3.0
Medicines Control, Provider Regulation

Legal entity	
Trading name	
Premises address	
Postal address	
District Health Board	
Proprietor/ Manager	
Contact details	
Date of audit	
Auditor(s)	
CAR forms issued	

Services
☐ Dispensing Services
☐ Compounding Services
☐ Repackaging Services
☐ Retail Pharmacy Services
☐ Online Pharmacy Services
☐ Remote Pharmacy Services
☐ Compliance Packaging Services
☐ Automated Packaging Services
☐ Clozapine Dispensing Services
☐ Opioid Substitution Treatment Services
☐ Aseptic Dispensing Services

Contents

Glossary

APC	Annual Practising Certificate
CAR	Corrective Action Request
CD	Controlled drug
CoE	Pharmacy Council Code of Ethics 2011
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
NSR	Health (Needle and Syringes) Regulations 1998
OST	Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008
OTC	Over-the-counter
PSA	Pharmacy Services Agreement (July 2012)
PSS	NZS 8134.7:2010 Health and Disability Services Pharmacy Services Standard
SAB	Still air box
SOP	Standard Operating Procedure

Note. Facilities/institutions include:
- **Rest homes-** certified age related residential care establishments (Health and Disability Services (Safety) Act 2001 S.6, 9 & 58).
- **Residential care facilities-** community based residential care establishments other than a rest home e.g. half way house or IHC flat.
- **Private hospitals-** privately owned acute care hospitals (Health and Disability Services (Safety) Act 2001 S.9 & 58).
- **Long stay hospitals-** certified geriatric hospitals (Health and Disability Services (Safety) Act 2001 S.9 & 58).
- **Prisons/Correctional facilities-** (Corrections Act 2004 S.32 (1) (a)).

Audit Framework

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

Level of attainment	
CI	Continued Improvement
FA	Fully Attained
PA	Partial Attainment
UA	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

A01 Licensing				
Criteria		**Attainment**	**Risk**	**Audit findings**
A01-01	**Is the current Licence to Operate Pharmacy on display to consumers?** *MA 54(1); PSA Schedule C1 Core Pharmacy Services 6.3*			
A01-02	**Are the following licensing details accurate?** (a) Site details (b) Responsible persons *MA 50(2), 51(1)(d); MR 48A*			
A01-03	**Is the pharmacy complying with additional conditions (c) onwards, if any, imposed on the licence?** *MA 52(3)*			
A01-04	**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*			
A01-05	**Is the pharmacist-in-charge of all pharmaceutical services provided by the organisation identifiable at all times?** *MA 42A; PSS 2.2.2; PSA G10(e); CoE 7.4, 7.5*			

A02 Staff				
Criteria		**Attainment**	**Risk**	**Audit findings**
A02-01	**Do all pharmacists have a current Annual Practising Certificate (APC)? Are there conditions?** *MR 42(1); HPCAA 8(1); PSS 2.5.2*			
A02-02	**Are all other staff suitably qualified or in a registered training programme (e.g., technicians, dispensary assistants, intern pharmacists)?** *MR 42(1), 42(1A); PSS 2.5, 5.2.5; PSA G9(b), Schedule C1 Core Pharmacy Services 6.5*			
A02-03	**Is there appropriate pharmacist supervision of non-pharmacist staff providing pharmaceutical services?** *MR 42(1A), PSS 2.5.1, 2.5.5, 2.6.1, 5.2.5, PSA G9(c, d)*			

Section B | Premises

B01 Premises				
Criteria		**Attainment**	**Risk**	**Audit findings**
B01-01	**Are the premises in a suitable condition, 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:** (a) smooth working surface (b) shelves, cupboards & drawers (internal & external) (c) sinks (including those used for hand washing) (d) floor(s) in the dispensing area(s) (e) smooth floor in the compounding area(s) (f) ceiling (including light fittings) (g) walls (including junction with other surfaces) *MA 51(1)(e); MR 29; PSS 4.2.5, 5.12.12; PSA G10(d)*			
B01-02	**Does the physical environment minimise the risk of harm (hazards?), aid independence, and appropriately meet the needs of service providers and the consumers?** *MA 51(1)(e); PSS 4.2.4; PSA G10*			
B01-03	**Are areas used by consumers and service providers ventilated, smokefree, lit and heated/cooled appropriately?** *MA 51(1)(e); MR 29(b); PSS 4.5; PSA G5.2*			
B01-04	**Is there a separate staff rest and refreshment room in the pharmacy?** (a) Is this room kept in a clean and tidy state? (b) If no room: Are there designated areas for eating, drinking and other non-dispensing/compounding practices that are kept in a clean and tidy state? *MA 47, 51(1)(e); MR 32, 36; PSS 4.2.3*			
B01-05	**Are accessible toilets conveniently located?** (a) Not opening directly into dispensing/compounding areas (b) Not used for storage (c) Clean, hygienic and maintained in a good state of repair *MA 51(1)(e); MR 29; PSS 4.3.1, 4.3.3*			
B01-06	**Are there adequate hand washing facilities:** (a) located in or immediately adjacent to all toilet areas (b) located in proximity to each service area **Is each hand washing facility provided with an adequate supply of:** (a) cold water & hot water at a safe and appropriate temperature to minimise the risk of harm (b) soap or other detergent (c) disposable towels or other suitable methods of hand drying *MA 51(1)(e); MR 29(i); PSS 4.3.1, 4.3.2, 4.3.3; PSA G10(d)*			

B01 Premises				
Criteria		**Attainment**	**Risk**	**Audit findings**
B01-07	**Is there sufficient security to ensure all medicines remain secure?** (a) When the pharmacy is open? - shoplifting - discourages uninvited access to dispensary (b) When the pharmacy is closed (including pharmacy within other premises)? (c) Is a monitored alarm system installed, that is independent of any shared areas? (d) Is the location of the alarm sensors suitable (e.g., covers dispensary and area where safe is located)? (e) Is there sufficient security and alarm coverage in the storage areas? *MA 42B, 51(1)(e); PSS 4.4.1, 4.4.4, 5.12.10*			
B01-08	**Are storage areas (including dispensary, retail and other storage areas) for medicines satisfactory and in a clean and tidy condition?** *MA 47, 51(1)(e); MR 29, 32*			
B01-09	**Do the storage area(s) provide appropriate & sufficient protection from:** (a) direct sunlight / light where applicable (b) moisture (c) insects, animals, vermin *MA 47, 51(1)(e); MR 29, 32; PSS 5.12.6, 5.12.13; PSA G10(a)*			

B02 Dispensary				
Criteria		**Attainment**	**Risk**	**Audit findings**
B02-01	**Is the dispensary:** (a) a distinct identifiable area? (b) of a size and layout that allows for efficient workflow and direct staff supervision? (c) maintained in an uncluttered and orderly manner (d) free of any material that is not required for dispensing? *MA 51(1)(e); PSS 5.12.1, 5.12.2, 5.12.8*			
B02-02	**Where a dispensing area is used for more than one activity:** (a) do these activities impose on each other? (b) are any activities undertaken that compromise the dispensing and compounding activities performed or the quality of final products? *MA 51(1)(e); PSS 5.12.2, 5.12.8*			
B02-03	**Are schedules for cleaning dispensing and compounding areas maintained, including for contract/non-pharmacy staff cleaners?** *MR 29(d); PSS 5.12.5*			

B03 Equipment				
Criteria		**Attainment**	**Risk**	**Audit findings**
B03-01	**Is all required dispensary equipment readily accessible at the premises?** (a) an electronic dispensing system with printer producing legible and durable labels (b) 3 stamped glass measures to include: - 10ml and - 25ml or 50ml and - 100ml (c) 2 tablet counting trays with suitable spatulas (including a dedicated tablet counting tray & spatula for the dispensing of cytotoxic medicines) (d) a refrigerator for storing medicines requiring refrigeration within the range 2-8°C (e) appropriate maximum-minimum temperature reading equipment for: - monitoring temperatures in refrigerator(s) used to store pharmaceuticals - monitoring ambient temperatures in all areas of the pharmacy used to store pharmaceuticals (f) Compounding equipment: - Class 2 balance (electronic or beam) to turn at 10mg, certified annually - metric weights certified annually: an appropriate set (10mg to 500g) if using a beam balance or at least two weights for validation purposes if using an electronic balance - Mortar and pestle - Stirring rod - Ointment slab - 2 spatulas suitable for compounding (steel handles are preferred) (g) any other equipment necessary for appropriate provision of services from the premises *MA 51(1)(e); Ministry of Health Guidelines for Pharmacy Equipment; PSS 5.14.7; PSA G10(b)*			
B03-02	**Are non-certified multi-use liquid measures validated?** *MA 51(1)(e); PSS 5.14.5*			
B03-03	**Are equipment and utensils (e.g. tablet counters, de-blistering machines) thoroughly cleaned, maintained and adequately stored?** *MA 51(1)(e); PSS 5.14.2*			
B03-04	**Is measuring, weighing, recording and control equipment calibrated and checked (e.g. tablet counters, de-blistering machines):** (a) at defined intervals by appropriate methods? (b) are adequate records of such tests maintained? *MA 51(1)(e); PSS 5.1.4, 5.14.4*			
B03-05	**Is dispensary equipment used for any other purpose than the preparation and dispensing of medicines?** *MA 51(1)(e); PSS 5.14.1*			

B03 Equipment				
Criteria		Attainment	Risk	Audit findings
B03-06	**Can the pharmacy demonstrate that the required reference resources are readily accessible at the premises?** (a) Concise information on individual medicines (b) Broad information on individual medicines (c) Clinical pharmacy/ Therapeutics (d) Drug interactions (e) Paediatric dosages of medicines (f) Drugs in pregnancy and breast feeding (g) Over the counter medicines (h) Herbal medicines **Are the inside covers of all printed reference resources marked with the pharmacy dispensing stamp?** *MA 51(1)(e); Ministry of Health Guidelines for Pharmacy Equipment*			
B03-07	**Can the pharmacy demonstrate that the current printed or electronic versions (including amendments or consolidated reprints) of the required legislation are readily accessible at the premises?** (a) Medicines Act 1981 (b) Medicines Regulations 1984 (c) Medicines (Standing Order) Regulations 2002 (d Misuse of Drugs Act 1975 (e) Misuse of Drugs Regulations 1977 (f) Health (Needles and Syringes) Regulations 1998 (g) Health (Retention of Health Information) Regulations 1996 (h) Health Practitioners Competence Assurance Act 2003 (i) Medicines (Designated Pharmacist Prescribers) Regulations 2013 (j) Medicines (Designated Prescriber: Nurse Practitioners) Regulations 2005 (k) Medicines (Designated Prescriber: Optometrists) Regulations 2005 (l) Medicines (Designated Prescriber - Registered Nurses Practising in Diabetes Health) 2011 Note. Pharmacies accessing www.legislation.govt.nz must be able to demonstrate that they have a mechanism in place for keeping up to date with amendments to the legislation. *MA 51(1)(e); Ministry of Health Guidelines for Pharmacy Equipment*			
B03-08	**Can the pharmacy demonstrate that the current printed or electronic versions of the required codes, standards and guidelines are readily accessible at the premises?** (a) NZS 8134.7:2010 Health and Disability Services Pharmacy Services Standard (b) Pharmacy Council Code of Ethics (c) Health Information Privacy Code 1994 (d) Code of Health and Disability Services Consumers' Rights *MA 51(1)(e); Ministry of Health Guidelines for Pharmacy Equipment*			

B03 Equipment				
Criteria		**Attainment**	**Risk**	**Audit findings**
B03-09	**Are suitable and appropriate containers available for the packaging of pharmaceutical products?** (a) How are the containers stored? (b) Are the containers clean? (c) Are safety containers used (where required)? *MA 44; MR 32, 33, 35, 37; PSS 5.2.3(d), 5.12.9, 5.21.1, 5.21.2; CoE 1.2, 1.12*			
B03-10	**Are maximum-minimum thermometers (including electronic devices e.g., datalogger) regularly validated?** (a) Are records of validation maintained? *MA 51(1)(e); Ministry of Health Guidelines for Pharmacy Equipment; PSS 5.14.4*			

Section C | Quality Management System

C01 Policies and Procedures				
Criteria		**Attainment**	**Risk**	**Audit findings**
C01-01	**Does the organisation have approved policies and SOPs that:** (a) are aligned with current good practice and service delivery (b) are readily accessible by staff (c) meet the requirements of legislation (d) are reviewed at appropriate regular intervals? *PSS 2.3.3, 2.3.4, 3.8.2, 5.10.3; PSA G3; CoE 7.8*			
C01-02	**Have SOPs for the dispensing and supply of pharmaceutical products (including repeats, owes, controlled drugs, PSOs) been 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*			
C01-03	**Is there an appropriate SOP for fridge temperature monitoring and cleaning?** (a) 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*			
C01-04	**Are there suitable SOPs for the processes of compounding:** (a) 'individual' (b) batch (if applicable) *PSS 5.15.1*			
C01-05	**Is there an appropriate SOP for repackaging?** *PSS 2.3.3, 5.27*			
C01-06	**Is there an appropriate SOP for the ordering and checking of incoming medicines (including starting materials)?** *PSS 2.3.3*			
C01-07	**Is there an appropriate SOP for ambient temperature monitoring, including actions to take if the temperature exceeds 25°C?** *PSS 5.4.1, 5.6.1(d), 5.13.2*			
C01-08	**Is there an appropriate SOP for handling and documenting medicine recalls?** *PSS 5.2.3(i)*			
C01-09	**Is there an SOP for the needle syringe exchange programme including reference to:** (a) dealing with clients (b) preventing and managing needle stick injuries (c) safe disposal of used needles *PSS 2.3.3; PSA G5.3(a)*			

C01 Policies and Procedures				
Criteria		**Attainment**	**Risk**	**Audit findings**
C01-10	**Does the pharmacy follow an appropriate SOP for infection control including reference to:** (a) cleaning schedules/procedures (b) waste management (e.g., gloves, cleaning bins) (c) hand washing/drying (eg, where, when, how) (d) needle stick injury prevention measures and procedures for action in case of needle stick injury (e) infectious disease policy (f) wound management (g) incident reporting (h) review plan for incidents? *MR 26, 27; PSA G5.3(a)*			
C01-11	**Is there an appropriate SOP for safe and appropriate storage and disposal of waste, including:** (a) general waste (b) confidential patient information (c) pharmaceuticals (d) cytotoxics (e) infectious/hazardous substances (f) sharps (g) use of protective equipment and clothing appropriate to the risks involved? *PSS 4.1.1*			
C01-12	**Are there appropriate SOPs for providing services to the depot(s)?** *PSS 2.3.3*			
C01-13	**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 Core Pharmacy Services 6.1(d)*			
C01-14	**Are SOPs available for dispensing compliance packed medicines that clearly outline:** (a) a description of the area used for compliance packaging (b) the frequency for cleaning/disposing of the area and equipment (e.g. gloves and forceps) (c) use of medication charts (d) checking and packing procedures that will minimise the possibility of errors (e) handling of medicine changes (f) pharmacist supervision and signoff at each stage of the operation (how is this recorded?) (g) management of medicines unsuitable for compliance packing (h) handling rejected packs (i) storage of finished packs (j) a system to identify non-compliant patients (k) provision to supply feedback to prescribers? *PSS 5.4, 5.36.4, 5.37.3, 5.42.1*			

C01 Policies and Procedures				
Criteria		**Attainment**	**Risk**	**Audit findings**
C01-15	**Does the Pharmacy have an appropriate SOP for the supply of pharmaceuticals or services to each facility and is this followed? Including:** (a) delivery (when, how and quantity supplied) (b) drug information service (c) emergency medical supplies (d) 'prn' medicines (contained in blister packaging where possible) (e) discontinued / returned medicines (including CDs) (f) maintenance of medication profiles (g) special storage items including: - refrigerated items - controlled drugs (appropriate packaging?) (h) liaison with facility staff and prescriber i.e. records of clinical interventions, delivery of medication, regular visits to the facility *PSS 3.2.3, 3.5.2, 5.2.1; PSA G3.1, G8*			
C01-16	**Are SOPs available for automated packaging of medicines that clearly outline:** (a) Procedure for cleaning all parts of the automated device (b) Procedures related to health, hygiene practices and clothing (c) Procedures for handling rejected packs (following GMP principles) (d) Procedures for filling canisters/exceptions trays (e) Maintaining records of filling of canisters/exceptions trays (f) Procedures for handling controlled drugs *PSS 5.42.1, 5.43.2, 5.46.1, 5.47.5*			
C01-17	**Is there an appropriate complaints SOP that includes reference to:** (a) the Code of Health and Disability Services Consumers' Rights (b) how consumers are made aware of the procedure for making a complaint (c) an appropriate form to record complaints (d) how these records are stored (e.g., folder) (e) who is the responsible person in the pharmacy (f) an appropriate review process and feedback to staff *HDC Right 10; PSS 1.11.1; PSA G6.1(b), G6.3*			
C01-18	**Are there appropriate SOPs for managing, documenting and reviewing pharmacy incidents (e.g. emergency and security conditions) and dispensing incidents (near-miss events and dispensing errors)?** **Do the SOPs include reference to:** (a) a definition of what constitutes a pharmacy incident: - incidents (including emergency and security conditions) - dispensing incidents (near-miss events and dispensing errors) (b) guidance for managing an incident (including who is responsible) (c) who should be contacted on identification of the incident (d) a description of how incidents are documented & a sample of the incident form(s) used (e) guidance following the incident (including but not limited to implementation of corrective actions, debriefing & counselling) (f) evaluation of the incident to ensure the corrective actions have been implemented and , with the aim of preventing future incidents (g) a system for regular review of all 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 7.9*			

C01 Policies and Procedures				
Criteria		**Attainment**	**Risk**	**Audit findings**
C01-19	**Is there an appropriate SOP describing the process for opioid substitution treatment dispensing and recording, including:** (a) the dispensing process (b) how liaison with the clinic is maintained (c) where 'consume on premises' doses are given out (d) record keeping (e) regular stocktake of methadone preparations *PSA G6.5, G8, Schedule C1 Pharmacy Methadone Services for Opioid Dependence 5.1(c)(vi); OST 11.10*			
C01-20	**Are SOPs maintained to control the aseptic dispensing process including:** (a) all key elements and manipulative steps to facilitate consistent production of a product of the required quality (b) following established and validated methods (c) clear, standardised and detailed documents (d) regularly reviewed (at intervals of not more than 2 years) (e) superseded documents clearly identified as such (f) procedure for recall *PSS 6.7*			
C01-21	**Is there an appropriate SOP for the dispensing of clozapine, including reference to:** (a) checking the patient is registered with the appropriate pharmaceutical company before supplying medication for the first time (b) maintaining individual records for each client, which are kept secure and confidential, both: - paper records; and - updating the provider database requirements (c) ensuring a satisfactory blood test result is available before dispensing each supply (d) the action to be taken if blood results are outside specified range (e) supplying the correct amount of medication according to when the full blood count was taken and when the client collects the medication (f) the action to be taken if problems arise (i.e. blood levels out of range, late, patient not collecting medication) (g) 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 C1 Pharmacy Clozapine Services, Schedule C2 Protocol for the Dispensing of Clozapine by Community Pharmacies*			

C02 Consumer Rights				
Criteria		**Attainment**	**Risk**	**Audit findings**
C02-01	**Is information about a consumer's right to complain and the complaints process available for consumers?** *PSS 1.11.2; PSA 6.1(a)*			
C02-02	**Is a complaints register maintained that includes all complaints, dates, and actions taken?** *PSS 1.11.3*			
C02-03	**Do consumers receive services in accordance with consumer rights legislation?** (a) Are consumers treated with respect and receive services in a manner that has regard for their dignity, privacy and independence? (b) 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 1.1, 1.3, 1.4; PSA G6.1, G6.2; CoE 4.9*			
C02-04	**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*			
C02-05	**Are all staff aware of the confidentiality of health information?** (a) That no unauthorised use may be made of it? (b) 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 2.7, 2.8*			

C03 Risk Management				
Criteria		**Attainment**	**Risk**	**Audit findings**
C03-01	**Are dispensing incidents (near-miss events & dispensing errors) consistently & appropriately documented?** *PSS 2.3.8, 3.8.1; CoE 5.4, 7.9*			
C03-02	**Are appropriate corrective actions implemented and reviewed to prevent future dispensing incidents?** (a) Is this documented? *PSS 2.3.1, 2.3.5, 2.3.7, 2.3.8, 2.4, 3.6.1, 3.6.2; PSA G5.4*			

C04 Training and Development				
Criteria		**Attainment**	**Risk**	**Audit findings**
C04-01	**Do service providers:** (a) have job descriptions (b) receive an orientation/induction programme (including locums) that covers the essential components of the service provided? *PSS 2.5.1, 2.5.4*			
C04-02	**Are service providers involved in on-going training and development? Do they receive appropriate information, training and equipment to respond to identified emergency and security conditions (including fire safety, emergency procedures and armed hold-ups)?** (a) Is this training documented? *PSS 2.5.5, 4.4.1, 5.10.2, 5.10.4; PSA G9(c)*			
C04-03	**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*			

Section D | Management of Pharmaceuticals

D01 Stock				
Criteria		**Attainment**	**Risk**	**Audit findings**
D01-01	**Are pharmaceuticals suitable for dispensing?** (a) obtained from a licensed wholesaler? (b) packaging not crushed/wet/damaged (c) stock stored in original containers? (If not, how is it stored and labelled, for example cut strips?) (d) returned stock recycled or reused? *MR 32, 34, 35*			
D01-02	**Does the pharmacy import/procure "new" (non-consented) medicines?** (a) Are certificates of analysis held and checked against the specifications of the product? (b) Are details of supply reported? *MA 29, 42*			
D01-03	**Is there a system for checking expiry dates of all stock (including controlled drugs, refrigerated & retail pharmaceuticals)?** (a) Is this system followed? *MR 32(2), PSS 3.8.1, 5.1.7*			
D01-04	**Does the pharmacy follow their SOP for handling medicine recalls and retain the record of recalls?** *PSS 5.2.3(i)*			
D01-05	**Is the refrigerator/cool room suitable for the storage of medicines, including for any products requiring critical monitoring?** (a) Clean (b) Frost-free (c) Foodstuffs stored appropriately to prevent cross-contamination. *MA 47, 51(1)(e); MR 32, 36; PSS 5.13.1, 5.13.3*			
D01-06	**Is the refrigerator maximum/minimum temperature appropriately and regularly monitored & documented to ensure maintenance within the range 2-8°C?** (a) Is there evidence of appropriate action taken if the temperatures have gone out of range? (b) If the monitoring is conducted external to pharmacy: - can pharmacy access temperature records? - is the pharmacy notified about temperatures outside the 2-8°C range *MA 51(1)(e); PSS 5.13.1, 5.13.4*			
D01-07	**Are ambient room maximum temperatures monitored and documented to ensure maintenance below 25°C?** (a) Is there evidence of appropriate action taken if the temperatures have gone out of range? (b) If the monitoring is conducted external to pharmacy: - can pharmacy access temperature records? - is the pharmacy notified about temperatures above 25°C? *MA 51(1)(e); PSS 5.13.1, 5.13.2; PSA G10(a)*			

D01 Stock				
Criteria		**Attainment**	**Risk**	**Audit findings**
D01-08	**Is there a clearly labelled/ designated area for quarantine of rejected/returned medicines?** *MA 51(1)(e); PSS 5.26*			
D01-09	**Is pharmacy waste disposed of appropriately?** (a) General waste (b) Confidential patient information (c) Pharmaceuticals (d) Cytotoxics (e) Infectious substances (f) Hazardous substances (g) Sharps (h) Use of protective equipment and clothing appropriate to the risks involved *MA 51(1)(e); MR 29(c); PSS 4.1, 4.2.4, 4.2.5, 5.11.1*			

D02 Controlled Drugs				
Criteria		**Attainment**	**Risk**	**Audit findings**
D02-01	**Are controlled drugs stored in a safe or substantial metal cabinet, which forms part of, or is securely fixed to the premises?** (a) If the safe is constructed of steel, does the safe comply with the Requirements for the Custody of Controlled Drugs in Steel Safes? *MA 51(1)(e); MoDR 28; Requirements for the Custody of Controlled Drugs in Steel Safes*			
D02-02	**Are all reasonable steps taken to ensure that controlled drugs are secure at all times?** (a) Location of safe? (b) Locked when not in immediate use? *MoDR 28*			
D02-03	**Is an approved form of controlled drugs register maintained?** (a) Where an approved recording system is used, are conditions of the approval met (e.g., transaction print-outs)? *MA 51(1)(f); MoDR 37, 44*			
D02-04	**Is a separate page used for each strength and form of controlled drug?** *MoDR 37(2)(a)*			
D02-05	**Are all transactions recorded within one business day?** *MoDR 40(1, 3)*			
D02-06	**Are corrections made in the approved fashion?** *MoDR 40(2, 4)*			
D02-07	**Is half yearly stock taking performed as at the close of business on the 30 June and 31 December every year?** *MoDR 43(1, 2)*			

D02 Controlled Drugs				
Criteria		**Attainment**	**Risk**	**Audit findings**
D02-08	**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)*			
D02-09	**Are records complete, accurate, current, legible and indelible?** (a) Are discrepancies accounted for? *MoDR 37, 40, 43*			
D02-10	**Do dispensed controlled drug prescription forms clearly record:** (a) stamped name and address of the pharmacy (b) date (printed or stamped) on each occasion on which the prescription is dispensed (c) identity of the individual dispensing the prescription (d) pharmacist responsible for the final check for completeness and accuracy? *MoDR 31(7, 8); PSS 5.2.3(f)*			
D02-11	**Are controlled drug prescriptions and register(s) retained for at least 4 years?** (a) In a neat and orderly manner? (b) On the premises? *MoDR 33, 42*			
D02-12	**Are destructions recorded in the controlled drugs register?** (a) patient returns (including date returned and date of destruction) (b) expired stock *MoDR 40(1)*			
D02-13	**Are obsolete or returned controlled drugs destroyed in an appropriate manner?** *MoDA 6, 7; MoDR 20; PSS 4.1.1; CoE 1.2 MoDR 40; PSS 4.1.1; CoE 1.2*			

Section E | Services

E01 Service Information				
Criteria		**Attainment**	**Risk**	**Audit findings**
E01-01	**Is appropriately written information available for Eligible People and other interested parties which describes:** (a) the services offered by the pharmacy (b) the location of these services (c) the hours of access (d) service users' rights and responsibilities (e) any other information to enable Eligible People to access the services *PSS 3.1.3; PSA G7.2*			
E01-02	**Is there a notice prominently displayed on the outer door or window specifying:** (a) when the Pharmacy is closed (b) how Eligible People can obtain essential pharmaceuticals during the period when the pharmacy is closed *PSS 3.1.2; PSA Schedule C1 Core Pharmacy Services 5.2(d)*			
E01-03	**Can printed information be provided to consumers about the needle syringe exchange scheme, and a list of providers in the local area?** *PSA Schedule C1 Core Pharmacy Services 6.1(b)(vi)*			

E02 Dispensing Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E02-01	**Is information of a private or personal nature maintained in a secure manner that is not publicly accessible or observable?** (a) If the pharmacy has an internet connection, has provision been made to ensure the security of confidential health information? (b) Are electronic prescription records maintained for a minimum of 10 years? Where? (c) Are there appropriate back-up and disaster recovery procedures to protect against the loss of information? (d) Storage of medicines awaiting collection? *MA 51(1)(f); MR 42(3)(l), 54A, 57, 58; HR 5, 6; PSS 2.7.4, 2.7.6; HIPC rules 5, 9; PSA G13.2*			
E02-02	**Is information entered into the dispensing program in an accurate and timely manner? Are secure, accurate and orderly records of prescriptions maintained?** *MA 51(1)(f); MR 42(3)(l), 57, 58; MoDR 33; PSS 2.7.1, 5.2.3(c); HIPC rules 4, 8; PSA Schedule C1 Core Pharmacy Services 6.1(c)*			
E02-03	**Is the use of generic medicine substitution controlled by agreed and documented policies? Does the pharmacist:** (a) record the brand substitution on the prescription? (b) sign and date the prescription? (c) inform the patient of the brand substitution? *MR 42(4); PSS 5.2.6; PSA Schedule C1 Core Pharmacy Services 3.2*			

E02 Dispensing Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E02-04	**Can the pharmacy demonstrate:** (a) awareness of the eligibility criteria as defined in the Pharmacy Services Agreement? (b) how to determine if an individual is an eligible person? *PSA C.3.1, G.7.1, H*			
E02-05	**Are all dispensing activities undertaken or directly supervised by a pharmacist?** *MR 42(1), 42(1A); PSS 5.2.3(a); CoE 7.1, 7.5*			
E02-06	**Does a pharmacist interpret and evaluate prescriptions for correctness and completeness, verify their authenticity and appropriateness?** *MoDR 29, 32(1); MR 39, 41; PSS 5.2.4*			
E02-07	**Is a signed authorisation received prior to dispensing?** (a) Are phone/fax prescriptions verified? (b) No repeats dispensed until original prescription received? (c) Obtained promptly as required by legislation? (d) Original matched and checked against telephone/fax prescription? *MoDR 34; MR 40A, 41, 42(3)(a); PSS 5.2.3(b)*			
E02-08	**Are emergency supplies of medicines made in accordance with legislative requirements?** *MR 44(m)*			
E02-09	**Are containers labelled with information for the consumer that meets legal and professional requirements, and, if prescribed, accurately reflect the prescribers instructions including:** (a) the name of, or a description of the nature of, the contents (b) name of patient (c) name and address of seller (d) dose and frequency of dose (internal medicine) (e) directions for use, frequency of use, and one or other of External Use Only'/'Not to be Taken' (external products) (f) unique identifying number (g) date on which medicine was packed, sold or supplied (h) quality and size of print (i) no abbreviations (j) cautionary & advisory information included *MR 12, 17, 18, 23; PSS 5.2.3(e)*			
E02-10	**Do dispensed prescription forms (including repeats and owes) clearly record:** (a) the name and address of the proprietor of the business at which the prescription is dispensed (b) the date on which the prescription is dispensed (c) the quantity of medicine dispensed (d) a unique identifying number or code for that prescription (e) the identity of the individual dispensing the prescription (f) the pharmacist responsible for the final check for completeness and accuracy *MR 42(3)(b); PSS 5.2.3(f)*			

E02 Dispensing Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E02-11	**Are proper controls used to ensure that the medicines prescribed are received (including delivery) by the intended person?** *PSS 5.2.3(g)*			
E02-12	**Are all reasonable steps taken to ensure:** (a) all essential professional advice and counselling is provided (b) that consumers have a sufficient knowledge to ensure optimal therapy (c) counselling is provided in private & professional manner *PSS 1.9.2; PSA G6.2, G6.5, Schedule C1 Core Pharmacy Services 6.1(b); CoE 1.7, 2.4, 3.3, 4.9*			
E02-13	**Are the details and outcome of issues identified with prescribing (prescription interventions) consistently documented?** (a) Could the system be used to retrieve a specific intervention in the case of a complaint or inquiry? *PSS 3.6.1, 3.6.3, 3.8.1; PSA G5,4; CoE 1.10, 7.10, 7.11*			

E03 Compounding Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E03-01	**Is compounding performed by a pharmacist? If compounding is performed by pharmacy graduates, pharmacy technicians and students, is this under direct personal supervision of a pharmacist?** *MR 63; PSS 5.9.2, 5.15.3*			
E03-02	**Is the compounding area clean, uncluttered and orderly?** (a) Are effective cleaning procedures used before commencing and at completion of product preparation? (b) Are adequate precautions taken to prevent contamination, cross-contamination and product mix-up in all stages of preparation? (c) Does the processing area only contain materials and documentation associated with the process being carried out? *PSS 5.12.2, 5.12.3, 5.12.4, 5.12.8, 5.15, 5.22, 5.27.1, 5.31*			
E03-03	**Can products be identified at all times during preparation? Are labels or indications on containers and equipment clear and unambiguous?** *PSS 5.15.6, 5.27.2*			
E03-04	**Does the pharmacist assign an appropriate expiry date with regards to the expected storage conditions?** *PSS 5.23, 5.32.1*			
E03-05	**Are starting materials:** (a) received with a manufacturer's expiry date discarded after this date? (b) purchased from recognised suppliers? (c) checked at the point of receipt? (d) checked at each occasion of use? (e) appropriate procedures or measures to assure the identity of the contents of each container? (f) damaged or contaminated considered by a pharmacist and appropriate action taken? *PSS 5.19*			

E03 Compounding Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E03-06	**Are starting materials that have been received without an expiry date assigned with a suitable expiry date and labelled with a date of receipt by the pharmacist?** *PSS 5.19.6*			
E03-07	**Are all starting materials stored under appropriate conditions and in an orderly fashion to permit identification, batch segregation and stock rotation?** *PSS 5.19.3, 5.19.7*			
E03-08	**When water is used as a starting material, is it of a quality appropriate for the finished product?** **If a water filter is used:** (a) is it maintained in compliance with the manufacturer's specifications? (b) is documentation of the filter replacements maintained? **If water for irrigation is used is it discarded within 24 hours of opening?** *MA 51(1)(e); MR 32; PSS 5.19.9, 5.19.10*			
E03-09	**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 for 3 years which enables the history of the finished product to be traced, including:** (a) the name of the preparation (b) name and quantities of the ingredients used (c) the date of the preparation (d) a unique identifying number (usually the prescription number) (e) the batch number and expiry date of each ingredient (f) the expiry date of the finished product (g) a copy of the product label (h) a quality check of the finished product including the signature or initials of the pharmacist checking/releasing the final product *MR 58; PSS 5.18.2, 5.23.1, 5.25, 5.34*			
E03-10	**Are labels that accurately describe the finished product attached to the container? Do the labels of individually compounded medicines contain:** (a) name of the pharmaceutical product (b) dosage form and strength where applicable (c) quantity in the container (d) instructions for use and storage (e) assigned batch number (e.g. prescription number) (f) expiry date of the finished product (g) date of compounding (h) name of pharmacy *PSS 5.24*			

E03 Compounding Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E03-11	**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 after the expiry date of the product, and include:** (a) the name of the product (b) the pharmaceutical form & strength of the product (c) a list of ingredients together with the amount of each (d) an area for the batch numbers & expiry dates of ingredients (e) a step-by-step description of the compounding procedure (f) the packaging material(s) to be used (g) the storage conditions for the finished product (h) a sample of the label and any advisory/auxiliary labels (i) the assigned expiry date period (j) an area for recording the batch quantity (k) an area for recording the unit pack size (l) an area for the batch number to be assigned (m) an area for sign off by a pharmacist for the measuring and checking of the ingredients (n) an area for reconciliation of final yield and labels (o) an area for sign off by a pharmacist for checking/release of final product *PSS 5.6.2, 5.16.4, 5.17.1*			
E03-12	**Are batch records maintained? Does the batch record contain the following information:** (a) date of preparation (b) name of the compounder (c) quantities of ingredients used (d) total quantity prepared (e) batch numbers and expiry dates of ingredients used (f) a unique identifying batch number (g) an expiry date of the finished product (h) a sample label and any auxiliary labels (i) any deviation from usual practice in preparation or ingredients used (j) a quality check of the finished product including the signature or initials of pharmacist checking/releasing finished product *PSS 5.18.1, 5.25, 5.34*			
E03-13	**Are labels that accurately describe the finished product attached to the container? Do the labels of batch compounded products contain:** (a) name of the pharmaceutical product (b) dosage form and strength where applicable (c) quantity in the container (d) instructions for use and storage (e) assigned batch number and expiry date (f) date of compounding (g) name of pharmacy *PSS 5.24*			

E04 Repackaging Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E04-01	**For products regularly repackaged, is there a master document (repackaging instruction) for each product, pack size and type including:** (a) name of the product (b) dosage form and strength (c) pack size (repacked product) (d) instructions for the unpacking and repacking procedure (including any applicable in-process controls) (e) a list of the packaging materials to be used (f) storage conditions for the repacked product (g) special precautions to be observed (h) labelling text or master reference label and any advisory/auxiliary labels (i) assigned expiry date period (repacked product) (j) an area for the original manufacturer's batch number and expiry date (k) an area for the in-house batch number and expiry date to be assigned (l) an area for sign off by a pharmacist for checking the label (m) an area for recording the product and packaging material quantities issued (n) an area for recording the product and packaging material quantities used or returned (o) an area for reconciliations of final yield, packaging materials and labels (p) an area for sign off by the pharmacist for checking/release of the final product *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 5.28.1*			
E04-02	**Are appropriate records for repackaging of medicines maintained, including:** (a) date of processing (b) name of the qualified staff member performing the operation (c) name/strength/dose form and material names to be recorded (d) quantities of all printed packaging materials, containers and bulk product, issues, used, destroyed or returned to stock (e) quantity of repackaged units prepared (f) a reconciliation for all components involved in the packaging procedure (g) batch number and expiry date of original product (h) assigned in-house batch number and expiry date of the repackaged product (i) a sample label and any auxiliary labels (j) the signature or initials of the pharmacist checking/releasing the finished product *PSS 5.29.1*			
E04-03	**Do labels for repackaged medicines that do not retain their original labelling, batch number and expiry date contain the following:** (a) name of the product (b) dosage form and strength where applicable (c) pack size (d) assigned batch number and expiry date (e) date of repackaging (f) name of the pharmacy *Note. Full labelling is only required for non-strip packaged medicine *PSS 5.32.2, 5.33.1*			

E04 Repackaging Services				
Criteria		Attainment	Risk	Audit findings
E04-04	**Is repackaged strip packed medicines that retain their original labelling, batch number and expiry date labelled with a minimum of the amount, name, strength and form of drug?** *PSS Repackaging of Medicines Principle, 5.27.2*			

E05 Retail Pharmacy Services				
Criteria		Attainment	Risk	Audit findings
E05-01	**Are OTC products with the potential for misuse appropriately stored/displayed in the pharmacy (e.g. Gee's Linctus, travel sickness medication, laxatives)?** *MA 51(1)(e); CoE 6.12; PCNZ Guidance: Advertising to the Consumer and Promotion of Products of Potential Misuse*			
E05-02	**Are staff aware of strategies for dealing with sales of scheduled medicines where misuse is suspected?** *CoE 6.13*			
E05-03	**Are sales of scheduled medicines appropriately supervised by a pharmacist?** *MA 42A; CoE 6.11*			
E05-04	**Are medicines repacked for OTC sale:** (a) appropriately labelled, including patient name, dispensing date and unique ID number or code? (b) labelled in response to a patient request (i.e. not on open display)? *MA 20; MR 23*			
E05-05	**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)*			
E05-06	**Does a pharmacist:** (a) have appropriate involvement in each sale of a restricted medicine? (b) provide appropriate advice in a private and confidential manner? *MA 18(1)(b); PSS 3.3.1*			
E05-07	**Do the records of sales comply with legal requirements, including:** (a) date of sale (b) buyers name and address (c) name & quantity of medicine sold (d) name of pharmacist taking responsibility for the sale *MR 54A, 55; HIPC Rule (1)a*			
E05-08	**If using a physical register, are past entries kept confidential when it is in use?** *HIPC Rule 4,5*			
E05-09	**If electronic, are the records retrievable for audit?** *MR 54A (2)(b)*			

E05 Retail Pharmacy Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E05-10	**Are sales of medicines such as ECP, trimethoprim and the administration of vaccines made by an accredited pharmacist?** (a) Is a record of supply kept (e.g. in the dispensary computer)? (b) Is the identity of the accredited pharmacist recorded? (c) Is the medicine labelled as if dispensed? *PCNZ Best Practice Guidelines for the Supply by Pharmacists of the Emergency Contraceptive Pill*			
E05-11	**Is the Pharmacy SOP for the needle syringe exchange programme followed?** *NSR 3, 9*			

E06 Online Pharmacy Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E06-01	**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*			
E06-02	**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'? Does the website display:** (a) the name of the licensed legal entity of the pharmacy (b) physical street address and all other contact details for the pharmacy (c) the name of the Charge Pharmacist? *PSS 3.9.2; PCNZ statement*			
E06-03	**Do pharmacists comply with legal requirements when giving advice or selling medicines via online contact?** (a) May only supply from a licensed pharmacy (b) Therapeutic claims must not be made for products unless they are consented medicines (c) Can only dispense prescriptions written by a NZ registered prescriber *MA 18, 32; PSS 3.9.3*			
E06-04	**Do pharmacists comply with professional and ethical obligations when providing online pharmacy services for Pharmacy-Only medicines and Restricted medicines?** (a) Who are the pharmacy selling to? (b) How is the pharmacist involved in the sale and how is this recorded? (c) How does the pharmacy check for multiple sales? *PSS 3.9.4*			
E06-05	**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*			

E07 Remote Pharmacy Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E07-01	**Does the pharmacy ensure the depot(s) are appropriately authorised (Authority to Possess Prescribed Medicines)?** *MA 43*			
E07-02	**How are prescriptions presented to the pharmacy?** (a) From legitimate source? (b) The original obtained promptly as required by legislation? *MA 18(2); PSS 5.2.3*			
E07-03	**Are medicines delivered to the depot packaged to protect consumer confidentiality?** **Does the pharmacy maintain a record of delivery including dispatch date, method of dispatch and address delivered to?** *MA 47; CoE 1.6, 2.7*			
E07-04	**Does the pharmacy ensure medicines are given to the correct person? For example:** (a) Does the depot maintain records of medicine collection? (b) Does the pharmacy receive a copy of these records? *MA 47; PSS 5.2.3*			
E07-05	**Are uncollected medicines returned to the pharmacy:** (a) In the timeframe as specified on the Authority? (b) Via a secure delivery system? *MA 47; PSS 5.2.1*			
E07-06	**Does the pharmacy provide access to counselling and advice?** *PSS 1.8, 5.2.5; CoE 1.6*			
E07-07	**Does the pharmacy provide on-going support to staff at the depot?** *PSS 2.5*			

E08 Compliance Packaging Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E08-01	**Is the designated area of a sufficient size to allow for separation of packing, checking and storage of finished packs?** *MA 51(1)(e); PSS 5.37.1*			
E08-02	**Is the area used thoroughly cleaned and cleared before and after the operation?** *PSS 5.37.3, 5.37.4*			
E08-03	**Are packs awaiting delivery, returned packs and packs awaiting change stored:** (a) in areas clearly labelled and distinct from one another to ensure there is no ambiguity over the status of a pack? (b) protected from light? (c) patient confidentiality ensured? *PSS 5.37.2*			

E08 Compliance Packaging Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E08-04	**Is a batch record kept for each medicine that is removed from its original blister packaging for later use in compliance packaging, including:** (a) date of de-blistering (b) name, strength and dosage form of the medicine (c) original batch number and expiry date of the medicine (d) identity of the person performing the procedure (e) identity of the pharmacist checking the end product (f) new assigned expiry date for the medicine in that container by the pharmacist *PSS 5.39.1, 5.39.2*			
E08-05	**Do labels of de-blistered medicines contain the following:** (a) name, strength and dosage form of the medicine (b) date the medicine was de-blistered and packed into the container (c) original batch number of the medicine (d) assigned expiry date *PSS 5.39.3*			
E08-06	**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*			
E08-07	**Does de-blistering of medicines only involve sufficient quantity for two week's use at a time?** *PSS 5.39.5*			
E08-08	**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*			
E08-09	**Are staff involved in all stages of the compliance packing procedure appropriately qualified as required by the Medicines Regulations and have received appropriate training?** *MR 42(1), 42 (1A); PSS 5.9, 5.36.1*			
E08-10	**Is documentation related to the prescription and compliance packaging completed before the packing operation is undertaken?** **If medication charts are created in the pharmacy and used for dispensing:** (a) are they checked against a current authorisation and signed by the pharmacist? (b) are medication changes documented? *PSS 5.38.1*			
E08-11	**For medication changes:** (a) is each new authorisation checked for accuracy by the pharmacist? (b) is this check recorded and retained in the pharmacy? *PSS 5.38.1, 5.38.2*			

E08 Compliance Packaging Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E08-12	**If pharmaceutical products are requested by the facility:** (a) are suitably authorised written orders received? (b) are these written orders received at least every 3 months and when changes occur? (c) are requests for 'as required' medications documented? (d) if changes occur, is the accuracy of patient records maintained? *PSS 2.7.5, 3.2.4, 5.38.1*			
E08-13	**For certified hospital institutions:** (a) is imprest stock ordered appropriately (e.g. is a written order received)? (b) are all relevant patient records retained by the pharmacy? *MoDA 8(f); MR 44(d)*			
E08-14	**Are only those medicines suitable for compliance packing dispensed into packs?** (a) Are medicines that are not suitable for compliance packing appropriately dispensed? *MR 32; PSS 5.36.2*			
E08-15	**At every stage of processing are products and materials protected from microbial and other contamination?** (a) ensure there is no direct contact with/contamination of the medication (e.g. use of gloves or forceps)? *MR 27, 29(d), 32(1), 34; PSS 5.36.3*			
E08-16	**Are packs checked and sealed as soon as practicable after filling, and sealed on the day of preparation?** *MR 32; PSS 5.36.5, 5.36.6*			
E08-17	**Are packs labelled with the following details:** (a) name of the consumer (b) name and address of the pharmacy (c) date of preparation of the pack (d) strength and name of all medications in the pack (e) prescription/reference number (f) directions for use; dose and frequency of dose of medication in the pack written in English (g) appropriate cautionary and advisory labels *MR 12, 17, 18, 23; PSS 5.40.1*			
E08-18	**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:** (a) consumer's name (b) name and strength of each medication contained in the dose unit (c) quantity of each medicine (d) dose time and day *PSS 5.40.2*			

E08 Compliance Packaging Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E08-19	**Is a final check undertaken by a pharmacist against the appropriate authorisation following the normal checking procedure for dispensed medicines? Does this include a check of:** (a) the foil/backing sheet? (b) both medicines and labelling? (c) is this check recorded on the pack? *PSS 5.41.1, 5.41.2*			
E08-20	**Is there a document retained in the pharmacy that records the identity of:** (a) The person dispensing/filling the pack? (b) The pharmacist responsible for the final check? *PSS 5.38.2, 5.41.2, 5.2.3(f)*			
E08-21	**Are compliance packs rejected at the final check quarantined until corrected and rechecked, or appropriately disposed of?** *PSS 5.41.3*			

E09 Automated Packaging Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E09-01	**Is adequate and suitable space available for the automated device to operate?** *MA 51(1)(e); PSS 5.42.5*			
E09-02	**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*			
E09-03	**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?** (a) Is training documented? (b) Are qualified staff performing the entry of the profile (cycle date, medicines to be packed, frequency, and dose, if signing sheets are required)? *MR 42(1), 42(1A); PSS 5.42.6, 5.43.1*			
E09-04	**Are documented records of cleaning the device according to the manufacturer's instructions maintained including:** (a) identity of the person (b) date and time *PSS 5.46.2*			
E09-05	**Is the automated device calibrated according to the manufacturer's specifications?** *MA 51(1)(e); PSS 5.42.7*			

E09 Automated Packaging Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E09-06	**Are critical steps of the process (including software systems) validated, including but not limited to:** (a) written specification from the manufacturer (b) documented procedures for filling canisters (c) written checking procedures including dates and identification of staff involved (d) filling reservoirs/canisters with medicines *PSS 5.42.2, 5.44.1*			
E09-07	**When reservoirs are filled is a record made of the:** (a) batch number and expiry date of the medicine (b) identification of the person filling the reservoir (c) date of filling *PSS 5.44.3*			
E09-08	**Before an exceptions tray is loaded into the automated device for packing, are the medicines checked for accuracy?** *PSS 5.44.4*			
E09-09	**Are reservoirs containing controlled drugs (e.g., codeine) appropriately handled?** (a) removed from device at end of process (b) stored in controlled drugs safe when not in immediate use *MoDR 28*			
E09-10	**Is there a system for identifying medicines that may not be suitable for processing through the automated device, including:** (a) cytotoxic medicines, antibiotics, hormones *PSS 5.44.2*			
E09-11	**Is a check of both medicines and labelling made against the appropriate authorisation, following the normal checking procedure for dispensed medicines within the pharmacy?** *PSS 5.47.1*			
E09-12	**Is each 'header' label for the entire dose pack appropriately labelled including:** (a) name of the consumer (b) name and address of the pharmacy (c) date of preparation of the pack (d) strength and name of all medications in the pack (e) prescription/reference number (f) directions for use; dose and frequency of dose of medication in the pack written in English (g) cautionary and advisory labels *MR 12, 17, 18, 23; PSS 5.47.3*			
E09-13	**If medicines are placed in individual sachets does the labelling of each individual sachet include:** (a) consumer's name (b) name and strength of each medication contained in the dose unit (c) quantity of each medicine (d) dose time and day *PSS 5.40.2, 5.47.4*			

E09 Automated Packaging Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E09-14	**Is thorough checking of the end product undertaken by a pharmacist before release of the product for supply? This should include checks for:** (a) accuracy (b) quality control (e.g. 'jumpers', chipped/broken tablets) *PSS 5.42.4*			
E09-15	**Is the checking process documented and retained on the pharmacy premises?** *PSS 5.47.2*			

E10 Clozapine Dispensing Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E10-01	**Does the pharmacy follow the SOP(s) for clozapine dispensing, including:** (a) checking the patient is registered with the appropriate pharmaceutical company before supplying medication for the first time (b) maintaining individual records for each client, which are kept secure and confidential, both: - paper records; and - updating the provider database requirements (c) ensuring a satisfactory blood test result is available before dispensing each supply (d) the action to be taken if blood results are outside specified range (e) supplying the correct amount of medication according to when the full blood count was taken and when the client collects the medication (f) the action to be taken if problems arise (i.e. blood levels out of range, late, patient not collecting medication) (g) maintaining a list of up to date contact telephone numbers for each patient *PSS 3.8.1, 3.8.2; PSA Schedule C1 Pharmacy Clozapine Services*			

E11 Opioid Substitution Treatment Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E11-01	**Are all variations to doses and changes to regimes authorised by the prescriber or key worker?** (a) are these authorisations retained (4 years)? (b) filed appropriately? *MoDR 24(1); OST 11.8*			
E11-02	**Is a valid prescription present for each dispensing?** (a) are dispensed prescriptions appropriately annotated, including the date of dispensing and identity of the pharmacist? *MoDR 24(1), 29, 31; OST 11.1, 11.3, 11.8*			
E11-03	**Is the measuring equipment (burette/syringe/Dispensette):** (a) appropriate and accurate (b) regularly validated using the stamped measures (c) appropriately cleaned after each use *OST 11.3, 11.4*			
E11-04	**Are takeaway doses dispensed in clean, new containers with child resistant closures (CRCs)?** *MR 35; OST 11.6*			
E11-05	**Is the collection of dispensings recorded in the pharmacy?** (a) Is there an audit trail up to and including handing over of takeaway doses? *OST 11.6*			
E11-06	**Do the labels meet requirements for:** (a) 'Consume on premises' doses (if prepared in advance) (b) takeaway doses *MR 23; OST 11.3, 11.6*			
E11-07	**Are 'consume on premises' doses provided appropriately?** (a) in an appropriate area within the pharmacy (b) identity of client checked (c) using disposable cups & water provided (d) supervised and observed by a pharmacist in a private and confidential manner *OST 11.3, 11.4; PSA Schedule c1 Pharmacy Methadone Services for Opioid Dependence 5.5(b)*			
E11-08	**Is waste disposed of appropriately?** (a) 'consume on premises' cups in a lined, covered rubbish bin, and where possible a biohazard container used? (b) confidential information? *PSA G5.3(a), G6.5(a); OST 11.4*			
E11-09	**Is storage appropriate for:** (a) Pharmacy stock (b) 'Consume on premises' & takeaway doses (c) Measuring equipment (burette/syringe/measure) *MR 28; OST 11.3*			
E11-10	**If any methadone solutions are compounded in the pharmacy, are:** (a) compounding records maintained? (b) proper entries made in the register? *MoDR 37, 40, 43; PSS 5.17.1, 5.18.1*			

E11 Opioid Substitution Treatment Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E11-11	**Is the recording system clear, easy to follow, and well maintained?** *MoDR 37, 39, 40; OST 4.11*			
E11-12	**If methadone recording sheets are used:** (a) is this an approved methadone recording system? (b) total(s) transferred to the controlled drug register daily? (c) retained on the premises for 4 years? (d) patient medication record completed and maintained for each patient? *MoDR 39, 42(1)*			
E11-13	**Are stock takes of methadone preparations sufficient to ensure an accurate balance can be maintained?** (a) Does this include explanations of stock adjustments? *MoDR 43*			

E12 Aseptic Dispensing Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E12-01	**Is a risk assessment conducted before any aseptic dispensing is undertaken?** *PSS 6.1*			
E12-02	**Is regular monitoring of the process and finished products undertaken, including microbiological analysis of finished products as appropriate?** *PSS 6.12*			
E12-03	**Are there sufficiently competent staff to carry out all the tasks required for aseptic dispensing?** *PSS 6.2.1; CoE 5.3, 7.1, 7.2*			
E12-04	**Before undertaking aseptic dispensing have all staff received training from a designated trainer or accredited provider in the appropriate skills and knowledge including:** (a) an appropriate knowledge of quality assurance processes (b) competence in the necessary manipulative skills (c) knowledge of pharmaceutical microbiology (d) a working knowledge of the products and services provided **Is this training documented?** *PSS 6.2.2, 6.2.3*			
E12-05	**Is the competence of staff assessed annually?** (a) Peer observation or an annual broth validation **Is revision or retraining provided by a designated trainer or accredited provider if necessary, for example:** (a) change of process and/or equipment (b) staff who have been absent from the aseptic dispensing process for 6 months or more *PSS 6.2.4, 6.2.6, 6.12.3*			

E12 Aseptic Dispensing Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E12-06	**Are infections and skin lesions assessed to determine whether the operator can safely dispense aseptic products?** *PSS 6.2.7*			
E12-07	**Is all aseptic dispensing carried out in a still air box (SAB), isolator, laminar flow unit, or other validated device?** *PSS 6.3.1*			
E12-08	**Is the device located in a dedicated area which is separate from the main pharmacy dispensing areas and areas of high traffic?** (a) Is it separate from such environments as wet areas, air flow, carpets or storage areas? *PSS 6.3.2*			
E12-09	**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*			
E12-10	**Does the dedicated area have sufficient space to allow the decontamination and transfer of equipment into the device?** *PSS 6.3.4*			
E12-11	**Is the device:** (a) able to be easily cleaned and disinfected (smooth and impervious surfaces) (b) cleaned regularly even when not in frequent use? (c) closed when not in use? *PSS 6.3.5, 6.3.6, 6.3.7*			
E12-12	**Is the isolator, laminar flow unit or other validated device used in accordance with any operating instructions?** *PSS 6.3.8*			
E12-13	**Do staff who are actively involved in the aseptic dispensing process wear appropriate clothing to minimise the risks of contamination?** (a) head coverings (to totally cover the hair) and masks (b) a non-shedding gown or apron worn to cover the critical area of the operator's body (c) no garments that create particles (e.g., woollen jumpers or jerseys) (d) all visible jewellery removed (e.g., wrist watches, bracelets and rings) (e) no cosmetics, nail polish, false nails (f) new head covering, mask, gown or apron and gloves used for each session *PSS 6.4*			
E12-14	**Is appropriate hand hygiene followed?** (a) wash hands, nails and arms to the elbows using an anti-bacterial scrub and water for a minimum of 2 minutes (b) dry hands and forearms using a non-linting cloth *PSS 6.4.7*			

E12 Aseptic Dispensing Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E12-15	**Are powder-free gloves worn that have been disinfected prior to use or are sterile?** **Are gloves:** (a) disinfected when removed from the work device or otherwise contaminated? (b) inspected for punctures or tears and replaced immediately if punctured or torn? *PSS 6.4.3*			
E12-16	**Are products discarded if gloves are punctured during the compounding process?** *PSS 6.4.8, 6.4.9*			
E12-17	**Is the device cleaned before the commencement of any aseptic dispensing session?** **Still air box (SAB):** (a) Spray all the inside surfaces and the lid with 70% alcohol (b) 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. (c) Replace the lid and let the alcohol dry for 2 minutes Other devices: (d) According to validated standard operating procedures *PSS 6.5.1, 6.5.2*			
E12-18	**Are batch records sufficient?** (a) to allow traceability of starting materials and components (e.g. a recall) (b) to establish an audit trail for the completed product (c) signed/initialled by the person who checked the calculations *PSS 6.6.2, 6.6.4*			
E12-19	**Are appropriate labels that accurately describe the aseptically dispensed product attached to the containers immediately following filling and closing of the syringe in the aseptic procedure & include:** (a) ingredients (b) total volume (c) infusion period (d) storage requirements (e) expiry date/time (f) batch number or other traceable identification (g) date of manufacture (h) name of the patient (i) name and address of the pharmacy (j) prescriber instructions *PSS 6.10.1, 6.10.2*			
E12-20	**Does the packaging ensure the integrity of the product and maintain asepsis?** (a) protection from gross contamination (b) protection from light (where necessary) (c) syringe(s) appropriately packaged for storage and transport *PSS 6.11*			

E12 Aseptic Dispensing Services				
Criteria		**Attainment**	**Risk**	**Audit findings**
E12-21	**Is there a defined step where the finished product is visually examined, compared with its specifications and released or rejected?** *PSS 6.8*			
E12-22	**Is the device workstation disinfected at the end of the dispensing process?** *PSS 6.5.4*			
E12-23	**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*			
E12-24	**Are products stored under refrigeration, normally 2-8°C, unless it would be detrimental to the product to do so?** *PSS 6.9.1*			
E12-25	**Are expiry dates assigned to all aseptic products according to known standards or literature?** *PSS 6.9.2*			
E12-26	**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*			