



OHSC

Office of Health Standards Compliance
Ensuring quality and safety in health care



REGULATORY CHC INSPECTION TOOL VERSION 1.2

PHARMACY / DISPENSARY



Facility:
Date:

- **Tool Name:** Regulatory CHC Inspection Tool 1.2
- **HEs Type:** CHC
- **Sector:** Public
- **Specialization:** CHC
- **Created By:** Health Standards Development and Training Unit

2 Pharmacy / Dispensary

Domain 2.1 USER RIGHTS

Sub Domain 2.1.1 4 User information

Standard 2.1.1.1 4(1) The health establishment must ensure that users are provided with adequate information about the health care services available at the health establishment and information about accessing those services.

Criterion 2.1.1.1.1 4(2)(a)(ii) The health establishment must provide users with information relating to service opening and closing times.

2.1.1.1.1.1 Legible signage at the entrance to the unit indicates the days and times when services are offered.

Assessment type: Observation - **Risk rating:** Essential measure

The opening and closing times must be displayed on a board or electronic screen at the entrance of the unit. The information must be clearly legible to an ambulant person and a person in a wheelchair. All internal signs must as a minimum be laminated. Text on signs must be typed, no hand written signs will be accepted. Signs do not need to be framed, but laminating must be in good condition with no turned corners or peeling. If frames are not used, posters must be neatly fastened to the wall. Not applicable: Never

Score	Comment

Sub Domain 2.1.2 5 Access to care

Standard 2.1.2.1 5(1) The health establishment must ensure that users are attended to in a manner which is consistent with the nature and severity of their health condition.

Criterion 2.1.2.1.1 5(2)(a) The health establishment must implement a system of triage.

2.1.2.1.1.1 The process to fast-track very sick, frail and elderly users to the front of the queue is implemented.

Assessment type: Observation - **Risk rating:** Essential measure

It must be evident from observing the activities in the waiting area that there is a process of assessing and determining the order in which patients should be seen, based on their need for care. The criteria used for this process must be explicitly stated either in a written or verbal manner to patients. Evidence of adherence to these criteria must be observed by inspectors. Not applicable: Where there were no very sick, frail and elderly care users during the time of inspection.

Score	Comment

Domain 2.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 2.2.1 6 User health records and management

Standard 2.2.1.1 6(1) The health establishment must ensure that health records of health care users are protected, managed and kept confidential in line with section 14, 15 and 17 of the Act.

Criterion 2.2.1.1.1 6(2)(b) The health establishment must ensure confidentiality of health records.

2.2.1.1.1.1 There is a 'No unauthorised entry' sign on the door of the pharmacy/dispensary.

Assessment type: Observation - **Risk rating:** Essential measure

Check if there is a sign that reads 'No unauthorised entry' on the pharmacy/dispensary door. All internal signs must as a minimum be laminated. Text on signs must be typed, no hand written signs will be accepted. Signs do not need to be framed, but laminating must be in good condition with no turned corners or peeling. If frames are not used, posters must be neatly fastened to the wall. Any other sign, e.g. 'Staff only', will be scored non-compliant. Not applicable: Never

Score	Comment

2.2.1.1.1.2 Access to the pharmacy/dispensary is controlled at all times.

Assessment type: Observation - **Risk rating:** Vital measure

The pharmacy/dispensary should have a lockable security gate or access-controlled door that only the pharmacy/dispensary personnel have access to. Those holding the keys/access cards/ access codes must keep it with them at all times and never leave it unattended. Not applicable: Never

Score	Comment

Sub Domain 2.2.2 7 Clinical management

Standard 2.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 2.2.2.1.1 7(2)(b) The health establishment must establish and maintain systems, structures and programmes to manage clinical risks.

2.2.2.1.1.1 CHECKLIST: Three users receiving medicine indicate that they have a clear understanding of how and when to take their medicine and any other relevant information.

Assessment type: Patient interview - **Risk rating:** Vital measure

Interview three users who have received medicines and ask them the questions below. Score 1 if the answer is 'yes' and 0 if the answer is 'no'.

Score	Comment

Unit 1 User 1

Aspects	Score	Comment
1. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain to you what each medicine is for?		

2. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain to you when to take your medicines?		
3. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain if you should take the medicine with or without food?		
4. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain to you the most common side-effects you could expect from the medicine?		
5. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant give you the opportunity to ask any questions or discuss anything that worries you about your medicine?		

Unit 2 User 2

Aspects	Score	Comment
1. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain to you what each medicine is for?		
2. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain to you when to take your medicines?		
3. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain if you should take the medicine with or without food?		
4. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain to you the most common side-effects you could expect from the medicine?		
5. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant give you the opportunity to ask any questions or discuss anything that worries you about your medicine?		

Unit 3 User 3

Aspects	Score	Comment
1. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain to you what each medicine is for?		

2. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain to you when to take your medicines?		
3. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain if you should take the medicine with or without food?		
4. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant explain to you the most common side-effects you could expect from the medicine?		
5. Did the pharmacist or post basic pharmacist's assistant or learner post basic pharmacist's assistant give you the opportunity to ask any questions or discuss anything that worries you about your medicine?		

2.2.2.1.1.2 There is no expired medicine on the shelves.

Assessment type: Observation - **Risk rating:** Vital measure

Check the expiry date of five medicines on the shelves of the pharmacy or dispensary. Score 0 if any expired medicines are found on the shelves. Not applicable: Never

Score	Comment

2.2.2.1.1.3 The licence for the pharmacy issued by the Director-General of the National Department of Health (NDoH) is available.

Assessment type: Document - **Risk rating:** Vital measure

This will promote user safety by ensuring that the unit meets all legal requirements. The licence issued by the Director-General of NDoH must be available (displayed or filed). For a dispensary a copy of the Pharmacy license the dispensary is linked with must be available. Not applicable: Never

Score	Comment

2.2.2.1.1.4 The current certificate of recording of a pharmacy or dispensary with the South African Pharmacy Council or proof of the annual fee payment is available.

Assessment type: Document - **Risk rating:** Vital measure

The current certificate of registration of the health establishment's pharmacy with the South African Pharmacy Council or proof that the annual fee payment is up to date and visibly displayed in the pharmacy or available in a file. Not applicable: Never

Score	Comment

2.2.2.1.1.5 The current certificate of registration of the responsible pharmacist for the health establishment with the South African Pharmacy Council is available.

Assessment type: Document - **Risk rating:** Vital measure

A pharmacy managed by a qualified and registered person will promote the safety of users and staff, as the pharmacy will be supervised by a skilled and knowledgeable person. The current certificate of registration with the South African Pharmacy Council of the responsible pharmacist or proof that payment of the annual fee is up to date and must be visibly displayed in the pharmacy or available in a file. For a dispensary a current copy of the responsible pharmacist certificate the dispensary is linked with must be available. Not applicable: Never

Score	Comment

2.2.2.1.1.6 Proof of registration of all pharmacist(s) and/or pharmacist's assistant(s) with the South African Pharmacy Council is available.

Assessment type: Document - **Risk rating:** Vital measure

The current certificate of registration with the South African Pharmacy Council of all pharmacist(s), pharmacist's assistant(s) or proof that payment of the annual fee is up to date and must be visibly displayed in the pharmacy or available in a file. Not applicable: Never

Score	Comment

2.2.2.1.1.7 Medicines dispensed for users are labelled in accordance with applicable legislation.

Assessment type: Observation - **Risk rating:** Vital measure

Instructions: Request permission from three users to assess the medication that has been dispensed on the day of the inspection. Check if medicine dispensed complies with the requirements below. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment

Unit 1 User 1

Aspects	Score	Comment
1. The labels of dispensed medicines are clear and legible		
2. The label affixed to the medicine does not obstruct or cover the expiry date		
3. The label affixed to the medicine contains the name of the user		

4. The label affixed to the medicine contains the name of the medicine		
5. The label affixed to the medicine contains the directions for use of the medicine		
6. The label affixed to the medicine contains the name and address of the health establishment where the medicine was dispensed		
7. The label affixed to the medicine contains the date of dispensing		

Unit 2 User 2

Aspects	Score	Comment
1. The labels of dispensed medicines are clear and legible		
2. The label affixed to the medicine does not obstruct or cover the expiry date		
3. The label affixed to the medicine contains the name of the user		
4. The label affixed to the medicine contains the name of the medicine		
5. The label affixed to the medicine contains the directions for use of the medicine		
6. The label affixed to the medicine contains the name and address of the health establishment where the medicine was dispensed		
7. The label affixed to the medicine contains the date of dispensing		

Unit 3 User 3

Aspects	Score	Comment
1. The labels of dispensed medicines are clear and legible		
2. The label affixed to the medicine does not obstruct or cover the expiry date		
3. The label affixed to the medicine contains the name of the user		

4. The label affixed to the medicine contains the name of the medicine		
5. The label affixed to the medicine contains the directions for use of the medicine		
6. The label affixed to the medicine contains the name and address of the health establishment where the medicine was dispensed		
7. The label affixed to the medicine contains the date of dispensing		

Standard 2.2.2.2 7(2) (b) A health establishment must establish and maintain systems structures and programmes to manage clinical risk.

Criterion 2.2.2.1 7 The health establishment implements process to ensure environmental cleanliness.

2.2.2.1.1 A cleaning schedule for the pharmacy or dispensary is available.

Assessment type: Document - **Risk rating:** Essential measure

Regular cleaning of the health establishment is an important aspect of infection prevention and control. The cleaning schedule should indicate which areas should be cleaned, how each area should be cleaned and how often. Not Applicable: Never

Score	Comment

2.2.2.1.2 Cleaning is carried out in accordance with the schedule.

Assessment type: Document - **Risk rating:** Vital measure

Check that the documented evidence of cleaning signed by the cleaners indicates that cleaning has been carried out in accordance with the cleaning schedule. Not applicable: Never

Score	Comment

2.2.2.1.3 All work completed is signed off by the cleaners.

Assessment type: Document - **Risk rating:** Essential measure

The cleaners must sign off areas that have been cleaned as required in the cleaning schedule. Monitoring tools (e.g. tick sheets) listing all cleaning tasks must be completed and signed for each room or area. Not applicable: Never

Score	Comment

2.2.2.1.4 All work completed is verified by the CHC manager or a delegated member of personnel.

Assessment type: Document - **Risk rating:** Essential measure

Daily inspections will ensure the cleanliness of the building. The person responsible for overseeing the cleaning service must inspect the building daily to confirm that cleaning has been carried out according to the schedule and that all areas attended to have been effectively cleaned. Monitoring tools (e.g. tick sheets) listing all cleaning tasks must be completed for each room or area. Not applicable: Never

Score	Comment

2.2.2.2.1.5 CHECKLIST: The pharmacy or dispensary is clean.

Assessment type: Observation - **Risk rating:** Vital measure

Use the checklist below to check whether the service area is clean. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment

Unit 1 Pharmacy or Dispensary

Aspects	Score	Comment
1. Windows are clean		
2. Window sills are clean		
3. The floor is clean		
4. Skirting boards are free of dust		
5. The countertops are clean		
6. The door handles are clean		
7. Mirrors are clean (where applicable) <i>Explanatory note: If the pharmacy/dispensary does not have mirrors, score this aspect NA (not applicable)</i>		
8. Walls are clean		
9. Bins are not overflowing		
10. Bins are clean		

11. The area is odour-free		
12. The area is free of cobwebs		
13. The shelves are clean		

Unit 2 Waiting area (score NA if there is no waiting area)

Aspects	Score	Comment
1. Windows are clean		
2. Window sills are clean		
3. The floor is clean		
4. Skirting boards are free of dust		
5. The countertops are clean		
6. The door handles are clean		
7. Mirrors are clean (where applicable) <i>Explanatory note: If the waiting area does not have mirrors, score this aspect NA (not applicable)</i>		
8. Walls are clean		
9. Bins are not overflowing		
10. Bins are clean		
11. The area is odour-free		
12. The area is free of cobwebs		
13. The shelves are clean		

Sub Domain 2.2.3 8 Infection prevention and control programmes

Standard 2.2.3.1 8(1) The health establishment must maintain an environment, which minimises the risk of disease outbreaks, the transmission of infection to users, health care personnel and visitors.

Criterion 2.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.

2.2.3.1.1.1 CHECKLIST: Hand washing facilities are available.

Assessment type: Observation - **Risk rating:** Vital measure

Use the checklist below to check whether the items listed below are available. Score 1 if the aspect is available and 0 if it is not available.

Score	Comment

Aspects	Score	Comment
1. Functional hand wash basin <i>Explanatory note: The basin should not be blocked, broken, or have deep cracks causing leaking of water</i>		
2. Taps are functional with running water		
3. Liquid hand wash soap		
4. Disposable hand paper towels		
5. A poster on hand hygiene is displayed above or next to the hand wash basin		
6. Alcohol based hand rub		

Sub Domain 2.2.4 9 Waste management

Standard 2.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 2.2.4.1.1 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

2.2.4.1.1.1 CHECKLIST: Waste is segregated as required by the waste management practices.

Assessment type: Observation - **Risk rating:** Essential measure

Use the checklist below to check if waste is segregated as required by the waste management practices stipulated in the National Environmental Health Norms and Standards. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment

Aspects	Score	Comment
1. General waste is discarded separately in a black or white or transparent plastic bag		
2. Pharmaceutical waste is discarded separately in a green container		

2.2.4.1.1.2 CHECKLIST: Expired or obsolete medicine is discarded according to prescribed procedures.

Assessment type: Observation - **Risk rating:** Vital measure

Observe if the health establishment complies with the procedure for discarding expired or obsolete medicine. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment

Aspects	Score	Comment
1. Expired or obsolete medicine is put in a dark green container marked with the words 'Pharmaceutical waste liquid or solid'		
2. The required documentation is attached to the container. <i>Explanatory note: This includes but is not limited to the name of the health establishment, the date the medicine was discarded, the name of the expired or obsolete medicine, strength, dosage form, quantity, expiry date for expired items and signature of the responsible person.</i>		

2.2.4.1.1.3 CHECKLIST: Sharps are safely managed and discarded in the pharmacy or dispensary.

Assessment type: Observation - **Risk rating:** Vital measure

Use the checklist below to check whether sharps are safely managed and discarded. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment	
Aspects	Score	Comment
1. Waste is properly segregated <i>Explanatory note: Only sharps and vials are discarded into the container; no other waste is observed in the container.</i>		
2. Sharps containers are discarded when they reach the limit mark		
3. Sharps containers are placed on a work surface or in wall-mounted brackets		
4. Sharps containers have correctly fitting lids		
5. Needles are not recapped before disposal <i>Explanatory note: This is not applicable for safety needles and syringes</i>		

Criterion 2.2.4.1.2 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

2.2.4.1.2.1 Appropriate containers for disposal of pharmaceutical waste are available.

Assessment type: Observation - **Risk rating:** Vital measure

A dark green container marked with the words 'Pharmaceutical waste liquid or solid' must be available in the pharmacy or dispensary. Not applicable: Never

Score	Comment

Domain 2.3 CLINICAL SUPPORT SERVICES

Sub Domain 2.3.1 10 Medicines and medical supplies

Standard 2.3.1.1 10(1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 2.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

2.3.1.1.1.1 CHECKLIST: The standard operating procedure for the management of medicines is available.

Assessment type: Document - **Risk rating:** Essential measure

Check the standard operating procedure for the management of medicines to see if the aspects listed below are included and explained. Score 1 if the aspect is included and explained, and 0 if it is not included or not explained.

Score	Comment	
Aspects	Score	Comment
1. Cleaning of the pharmacy/dispensary		
2. Storage and organisation of the pharmacy/dispensary		
3. Security and control of access to the pharmacy/dispensary (within and outside normal working hours)		
4. Cold chain management		
5. Emergency medicine cupboard or trolley management		
6. Management of medicines in the consulting room		
7. Pest control		
8. Calculation and use of minimum, maximum and/or re-order levels		
9. Completion and management of stock (bin) cards and/or electronic stock monitoring system		
10. Stock taking (counting) procedure		
11. Management of short-dated stock		
12. Procurement (ordering) of medicines		
13. Order and delivery schedule		
14. Receipt of medicines into the pharmacy/dispensary (ordered or borrowed stock)		
15. Managing return of stock to the depot		
16. Issuing of medicines to the consulting rooms, procedure room and emergency trolley		
17. Managing stock transfers between health establishments		

18. Medicine availability monitoring procedure/guideline		
19. Separation and handling of expired, obsolete, unusable or userreturned medicines (Schedule 0 to 4 medicines)		
20. Disposal of expired, obsolete, unusable and user-returned medicines (Schedule 0 to 4 medicines)		
21. Managing recall of medicines		
22. Storage and control of Schedule 6 medicines		
23. Separation and disposal of expired, obsolete and unusable medicines (schedule 5 and schedule 6 medicines)		

2.3.1.1.1.2 CHECKLIST: The electronic network system for monitoring the availability of medicines is used effectively.

Assessment type: Observation - **Risk rating:** Essential measure

Use the checklist to check whether the electronic network system for monitoring the availability of medicines is used effectively. The electronic systems can include but are not limited to Stock Visibility System (SVS), RX Solutions and JAC. To determine whether the health establishment has reported the availability of medicines as required, visit the website used to view captured medicine availability data, and the Primary Health Care Health Establishment Dashboard associated with it. Score 1 if the aspect is compliant and score 0 if it is not compliant.

Score	Comment	
Aspects	Score	Comment
1. The health establishment has a functional electronic network system for monitoring the availability of medicines		
2. The approved list of medicines to be updated is visible in the electronic network system		
3. The capturing device is in good working order		
4. The accessories are in good working order		
5. The capturing device is stored in a lockable unit (only applicable to SVS)		
6. Accessories for the device, i.e. batteries and charger, are stored in a lockable unit (only applicable to SVS)		
7. Access to the keys for the unit where the capturing device and its accessories are stored is restricted (only applicable to SVS)		

<p>8. In the last seven working days or more this health establishment has not been marked as non-reporting at the point of assessment</p> <p><i>Explanatory note: The source for the information will be the website used to view the availability of captured medicine data and the associated Primary Health Care health establishment dashboard. The SVS cell phone will show last reporting date (only applicable to SVS).</i></p>		
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2.3.1.1.1.3 Re-ordering stock levels (minimum/maximum and/or reorder levels) are determined for each item on the District/health establishment formulary.

Assessment type: Document - **Risk rating:** Vital measure

Each item held as stock should have documented minimum, maximum and/or re-order levels. These levels should be recorded on the bin cards or equivalent. The system can be manual or electronic. Not applicable: Never

Score	Comment

2.3.1.1.1.4 There is evidence that a stock take of medicine was done in the last 12 months.

Assessment type: Document - **Risk rating:** Vital measure

Documented evidence of a formal stock take will be required, i.e. a certificate or report, indicating that a stock take has been completed in the last 12 months. Not applicable: Never

Score	Comment

2.3.1.1.1.5 Schedule 6 medicines in stock correspond with the balance recorded in the register.

Assessment type: Observation - **Risk rating:** Vital measure

Select three medicines from the Schedule 6 medicine cupboard and check for correspondence with the register. If the medicines do not correlate, this measure will be scored 0. Not applicable: Where Schedule 6 medicines are not held at the health establishment

Score	Comment

Criterion 2.3.1.1.2 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

2.3.1.1.2.1 CHECKLIST: 90% of medicines on the tracer medicine list are available.

Assessment type: Observation - **Risk rating:** Vital measure

All community health centres must hold stock according to the Tracer Medicine List as a routine. Should medicines be out of stock, substitutions will only be accepted if documented evidence of the recommended substitute from the District pharmacist is available. Alternatively, where the tracer medicine list recommends several medicines as equivalent for treatment, substitutions from this list of recommended medicines will be acceptable without a letter from the District pharmacist. Routine use of alternative dosages or formulations will be scored non-compliant. Check in the pharmacy/dispensary to see if the tracer medicines listed below are available. Score 1 if the item is in stock and not expired and 0 if it is not in stock or if it is expired.

Score	Comment	
Aspects	Score	Comment
Oral formulations/inhalers		
1. Abacavir 20mg/ml solution or Abacavir 60 mg dispersible tablets		
2. Abacavir 300mg tablets		
3. Amoxicillin 250mg capsules		
4. Amoxicillin 500mg capsules		
5. Amoxicillin 125mg/5ml or 250mg/5ml suspension		
6. Azithromycin 250mg or 500mg tablets		
7. Beclomethasone/Budesonide 100mcg or 200 mcg metered dose inhaler (MDI)		
8. Carbamazepine 200mg tablets or Lamotrigine 25mg tablets		
9. Co-trimoxazole 200/40mg per 5ml suspension		
10. Co-trimoxazole 400/80mg tablets		
11. Efavirenz 200 mg capsules		
12. Efavirenz 50mg capsules		
13. Enalapril 5mg or 10mg tablets		

14. Ferrous lactate/gluconate liquid/syrup		
15. Ferrous sulphate (dried) /fumarate tablets providing \pm 55 to 65mg elemental iron		
16. Folic acid 5 mg tablets		
17. Hydrochlorothiazide 12.5mg or 25mg tablets		
18. Ibuprofen 200 mg or 400 mg tablets		
19. Isoniazid 100mg or 300 mg tablets		
20. Lamivudine 10mg/ml solution		
21. Lamivudine 150mg tablets		
22. Combined oral contraceptive pill containing 30 mcg ethinylestradiol) ethinylestradiol/levonorgestrel or ethinylestradiol/norethisterone or ethinylestradiol/gestodene or ethinylestradiol/norgestimate		
23. Lopinavir, Ritonavir 200/50mg tablets or Atazanavir 150mg capsules WITH Ritonavir 100mg capsules		
24. Lopinavir, Ritonavir 80/20mg/ml solution		
25. Metformin 500mg tablets		
26. Metformin 850mg tablets		
27. Methyldopa 250 mg tablets		
28. Metronidazole 200mg or 400mg tablets		
29. Nevirapine 200mg tablets		
30. Nevirapine 50mg/5ml suspension		
31. Oral rehydration solution		

32. Paracetamol 120mg/5ml syrup		
33. Paracetamol 500mg tablets		
34. Prednisone 5mg tablets		
35. Pyrazinamide 500mg tablets		
36. Pyridoxine 25mg tablets		
37. Rifampicin + Isoniazid (RH) 300mg/150mg or 150/75mg tablets		
38. Rifampicin + Isoniazid (RH) 60/60 tablets or Rifampicin + Isoniazid (RH) 75/50 tablets or Rifampicin + Isoniazid (RH) + pyrazinamide (RHZ) 75/50/150 tablets		

39. Rifampicin + Isoniazid + pyrazinamide + ethambutol (RHZE) (150/75/400/275) tablets		
40. Salbutamol 100 mcg MDI		
41. Simvastatin 10mg or 20 mg or 40mg tablets		
42. Tenofovir/emtricitabine/efavirenz 300/200/600mg tablets		
43. Tenofovir/emtricitabine 300/200 mg tablets		
44. Vitamin A 50,000U capsules or Vitamin A 100,000U capsules or Vitamin A 200,000U capsules		
45. Zidovudine 50mg/5ml, 200 ml suspension		
Injections		
46. Benzathine benzylpenicillin 1.2MU or 2.4MU vial		
47. Ceftriaxone 250 mg or 500 mg or 1g vials		

48. Medroxyprogesterone acetate 150mg/ml injection or norethisterone 200mg/ml		
Topicals		
49. Chloramphenicol 1%, ophthalmic ointment		
Refrigerator		
50. BCG vaccine		
51. Insulin, short acting		
52. Measles vaccine		
53. Hexavalent: DTaP-IPV-HB-Hib vaccine		
54. Oxytocin 5 or 10 IU/ml AND Ergometrine 0.5mg or oxytocin/ ergometrine 5U/0.5mg combination		
55. Pneumococcal Conjugated Vaccine (PCV)		
56. Polio vaccine (oral)		
57. Rotavirus vaccine		
58. Tetanus toxoid (TT) vaccine		
Emergency medicine		
59. Activated Charcoal		
60. Adrenaline 1mg/ml (Epinephrine) 1ml ampoule		
61. Amlodipine 5mg or 10mg tablets		
62. Aspirin 100mg or 300mg tablets		

63. Atropine 0.5mg or 1mg ampoule		
64. Calcium Gluconate 10% 10ml ampoule		
65. 50% dextrose (20ml ampoule or 50ml bag) or 10% dextrose 1L solution		
66. Furosemide 20mg or 10mg/2ml ampoule		
67. Hydrocortisone 100mg/ml or 200mg/2ml vial		
68. Prednisone 5 mg tablets		
69. Ipratropium 0.25mg/2ml or 0.5mg/2ml Unit dose vial for nebulisation		
70. Lidocaine/Lignocaine IM 1% or 2% 20ml vial		
71. Magnesium sulphate 50%, 1g/2ml ampoule (minimum of 14 ampoules required for one treatment)		
72. Midazolam (1mg/ml 5ml ampoule or 5mg/ml 3ml ampoule) or Diazepam 5mg/ml 2ml ampoule		
73. Nifedipine 5mg or 10mg capsules		
74. Neonatalyte 200ml solution		
75. Paediatric solution e.g. ½ strength Darrows (200ml or 500ml) solution		
76. Promethazine 25mg/2ml or 25mg/1ml ampoule		
77. Short acting sublingual nitrates e.g. glyceryl trinitrate SL or isosorbide dinitrate sublingual, 5 mg tablets		
78. Salbutamol 0.5% 20ml nebulising solution or 2.5mg/2.5ml or 5mg/2.5ml Unit dose vial for nebulisation or Salbutamol 100 mcg MDI		
79. Sodium chloride 0.9% 1L solution		

80. Thiamine 100mg/ml 10ml vial		
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2.3.1.1.2.2 CHECKLIST: The temperature of the pharmacy or dispensary is maintained within the safety range.

Assessment type: Document - **Risk rating:** Vital measure

Use the checklist below to check whether the temperature in the pharmacy/dispensary is maintained between 15 and 25 degrees Celsius. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment	
Aspects	Score	Comment
1. The temperature of the pharmacy or dispensary is recorded daily. <i>Explanatory note: This is to assess if the health establishment consistently monitors the room temperature. Request temperature monitoring sheets from the previous three months.</i>		
2. The temperature of the pharmacy/dispensary is maintained between 15 and 25 degrees Celsius		

2.3.1.1.2.3 CHECKLIST: Procedures to maintain the cold chain for vaccines are implemented.

Assessment type: Observation - **Risk rating:** Vital measure

Use the checklist below to check whether the cold chain for vaccines is maintained. Score 1 if compliant with the aspect below and score 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. The pharmacy or dispensary has a vaccine or medicine refrigerator with a thermometer. <i>Explanatory note: The vaccine or medicine refrigerator can be located in any space in the CHC, a domestic refrigerator will be scored noncompliant.</i>		
2. The temperature of the refrigerator is recorded twice daily, seven hours apart (check three months records)		
3. The temperature of the refrigerator is maintained between 2 and 8 degrees Celsius (check three months records)		
4. There is a cooler box for storage of vaccines		

5. Ice packs are available for use		
6. There is a functional thermometer for use in the cooler box		

2.3.1.1.2.4 CHECKLIST: Three scripts in the pharmacy or dispensary are correlated with the medicines dispensed to ensure that all medicines were received as prescribed.

Assessment type: Patient record audit - **Risk rating:** Vital measure

Select three user scripts in the pharmacy/dispensary and check whether medicines were dispensed against this script. If all medicines as prescribed were dispensed, score 1. If a user has not received all the medicines as prescribed, score 0.

Score	Comment	
Aspects	Score	Comment
1. User 1		
2. User 2		
3. User 3		

2.3.1.1.2.5 There is at least one functional room thermometer.

Assessment type: Observation - **Risk rating:** Vital measure

A functional thermometer is available. Not applicable: Never

Score	Comment

2.3.1.1.2.6 The register for Schedule 6 medicines is completed correctly.

Assessment type: Document - **Risk rating:** Vital measure

Accurate, comprehensive recording of dispensing of Schedule 6 medicines is a legal requirement and must be done in accordance with the applicable legislation. All columns in the provincially provided registers must be comprehensively completed. Any omitted information noted during the review of the register will result in a non-compliant score. The inspector must confirm that all sections of the register have been completed correctly. If any of the columns have not been completed, this measure will be scored 0. Not applicable: Where schedule 6 medicines are not held at the health establishment.

Score	Comment

Domain 2.5 FACILITIES AND INFRASTRUCTURE

Sub Domain 2.5.1 14 Management of buildings and grounds

Standard 2.5.1.1 14(1) The health establishment and their grounds must meet the requirements of the building regulations.

Criterion 2.5.1.1.1 14(2)(d) The health establishment must as appropriate for the type of buildings and grounds of the establishment have ventilation systems that maintain the inflow of fresh air, temperature, humidity and purity of the air within specified limits set for different service areas such as theatres, kitchen and isolation units.

2.5.1.1.1.1 The pharmacy or dispensary has a functional air conditioner.

Assessment type: Observation - **Risk rating:** Vital measure

Check if the air conditioner switches on and off and provides cold/cool air to the room in accordance with the temperature setting.

Not applicable: Never

Score	Comment

Sub Domain 2.5.2 15 Engineering services

Standard 2.5.2.1 15(1) The health establishment must ensure that engineering services are in place.

Criterion 2.5.2.1.1 15(2) The health establishment must have 24-hour electrical power, lighting, medical gas, water supply and sewerage disposal system.

2.5.2.1.1.1 There is functional back-up electricity supply to the refrigerator(s).

Assessment type: Document - **Risk rating:** Vital measure

This is to ensure provision of uninterrupted power supply to the refrigerators. Records of monitoring of the availability of emergency power during power disruptions must be kept. Records should demonstrate the date and time of power disruptions and indicate if emergency power was available or not. Not applicable: Never

Score	Comment

Official Sign-Off

The National Health Act, 2003 (Act No. 61 of 2003) provides for quality requirements and standards in respect of health services provided by health establishments to the public. The main objective is to promote and protect the health and safety of the users of health services and contribute to improved outcomes and improved population health.

To achieve this mandate standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Community Health Centre(CHC).

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- The Certification and Enforcement Committee of the OHSC Board for reviewing the tools and for recommending to the Board for approval.

It is hereby certified that these Regulatory Community Health Centres(CHC) Inspection tools version 1.2 was developed by the Office of Health Standards Compliance.

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Executive Manager
Health Standards Development Analysis and Support
Date: 17/02/2021

Signature:



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Date: 17/02/2021

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