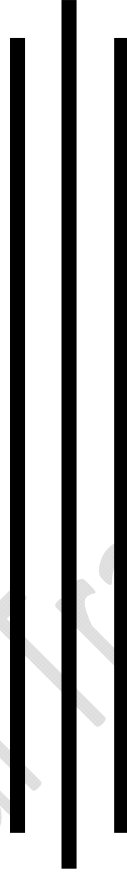


HOSPITAL PHARMACY SERVICE GUIDELINE, 2072



Government of Nepal
Ministry of Health and Population
Ramshahpath, Kathmandu

Unofficial Translation

Hospital Pharmacy Service Guideline, 2072

Preamble:

The Government of Nepal has made the following guidance exercising the right given by the Good Governance (Management and Operations) Act, 2064, Section 45 in order to ensure access to health services for all in an effective manner by providing accessible and quality service to patients and clients through the operation of its own pharmacy service by hospitals through human resource qualified in the subject of pharmacy.

1. Short Title and Commencement:

- (1) This guideline shall be called “Hospital Pharmacy Service Guideline, 2072.”
- (2) This guideline shall be effective from the date of approval by the Government of Nepal.

2. Definition: In this guideline, unless the subject or the context means otherwise:

- (1) “Ministry” means the Ministry of Health and Population.
- (2) “Hospital” means any government hospitals and health centres that are under a complete or partial proprietorship or control of the Government of Nepal, or those in operation according to the Development Committee Act, 2013.
- (3) “Pharmacy Service” means the service in operation or to be operated in the Hospitals that is delivered through a medicine and medicinal substance or material.
- (4) “Committee” means the Hospital Pharmacy and Therapeutic Committee formed according to Section (3).
- (5) “Hospital Formulary” means a detailed booklet of medicines and medicinal substances or materials used in the Hospital.

3. Hospital Pharmacy and Therapeutic Committee: The following Hospital Pharmacy and Therapeutic Committee shall be formed to operate the service delivered through medicines and medicinal substances or materials in the Hospital effectively and systematically.

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|--|--------------------|
| (A) Hospital Chief or a Senior Physician authorized by him/her | - Chairperson |
| (B) Chiefs of medical departments or units | - Member |
| (C) Chief looking after nursing function | - Member |
| (D) Administration Section Chief | - Member |
| (E) Financial Administration Section Chief | - Member |
| (F) Hospital Pharmacy Chief | - Member Secretary |

4. Function, Duty and Right of the Committee: The function, duty and right of the Committee will be as follows:

- (A) To determine a list of medicines and medicinal substances or materials to be put in the hospital pharmacy.
- (B) To determine pre-qualified manufacturers and suppliers of medicines or medicinal substances or materials as required.

- (C) To approve or disapprove a particular brand according to reliability of its quality.
- (D) To approve or revise the Hospital Formulary.
- (E) To monitor an adverse drug reaction.
- (F) To prepare a protocol pertaining to a treatment service being provided by the Hospital.
- (G) To prepare a format of prescription with a list of drugs based on the Hospital Formulary.
- (H) To inspect and monitor the hospital pharmacy from time to time.
- (I) To implement or have a directive from the Ministry regarding the operation of the hospital Pharmacy Service implemented.

5. Provision Related to Committee Meeting:

- (1) A meeting of the Committee shall convene at least once every two months.
- (2) At least forty-eight hours prior to the meeting of the Committee, the Member Secretary must provide all members with a meeting agenda.
- (3) The presence of more than fifty percent of the members shall be considered a quorum for a meeting proceeding.
- (4) A meeting shall be chaired by the Committee Chairperson.
- (5) A decision of the Committee shall be based on the vote from the majority of members present. In an event of a tie, the Chairperson shall cast a decisive vote.
- (6) The decision of the Committee meeting shall be attested by the Member Secretary.
- (7) Other procedures pertaining to the Committee meeting shall be as determined by the Committee itself.

6. Hospital Pharmacy Operation Committee:

- (1) To operate the hospital pharmacy in organized manner, a Pharmacy Operation Committee shall be formed as the following:
 - (a) Hospital Pharmacy Chief - Coordinator
 - (b) Financial Administration Chief or his/her representative - Member
 - (c) Chief of Procurement Section or his/her representative - Member
 - (d) Staff appointed by Hospital Pharmacy Chief - Member Secretary
- (2) The function, duty and right of the Committee formed as per Sub-section (1) shall be as determined by the Hospital Pharmacy and Therapeutic Committee.
- (3) A meeting operation procedure of the Committee formed as per Sub-section (1) shall be as determined by the Hospital Pharmacy Operation Committee itself.

7. Function, Duty and Right of Pharmacy Chief: The function, duty and right of the Pharmacy Chief shall be as follows:

- (A) To implement or have the decisions of the Committee implemented.
- (B) To prepare and present a proposal for a Committee meeting.

- (C) To prepare or have a list of drugs for use in the Hospital prepared.
- (D) To facilitate clinical pharmacy service delivery.
- (E) To supervise subordinate staff.
- (F) To periodically verify or have inventory and near expiry drugs verified and manage or have sales managed.
- (G) To carry out other functions as determined by the Committee.

8. **Procurement Procedure of Medicine and Medicinal Substance and Material:** The procurement of a medicine and medicinal substance and material shall be conducted following Public Procurement Act, 2063, and Public Procurement Rules, 2064.

9. **Sales Price of Medicine and Medicinal Substance:** While determining a sales price of a medicine and medicine related substance, it shall be determined by adding no more than twenty percent to a cost price. But while determining a sales price in this way, it must not exceed a maximum retail price (MRP).

10. **Human Resource for Hospital Pharmacy:**

- (1) The Hospital must arrange permanent human resources for the operation of the pharmacy.
- (2) Notwithstanding Sub-section (1), till permanent human resources are available, there shall be no objection to operate Pharmacy Service through an alternative arrangement.
- (3) The Hospital shall fulfil permanent staff from Nepal health service and other necessary staff according to the existing rule.
- (4) The following minimum human resources shall be available for the operation of the pharmacy:

No.	Hospital/Health Institution	Clinical* Pharmacist	Pharmacist	Assistant Pharmacist	Helper
1	Hospital with more than 100 beds	1	3	6	2
2	Hospital with 51 to 100 beds	1	2	4	2
3	Hospital with 26 to 50 beds	-	1	2	1
4	Hospital with 15 to 25 beds	-	-	2	1

*Explanation: For the purpose of this Section, Clinical Pharmacist refers to the person who has completed post-graduation in clinical pharmacy or pharmaceutical care or PharmD following B. Pharmacy.

- (5) Notwithstanding Sub-section (4), the hospital pharmacy may add or reduce the human resources according to the hospital beds, workload and daily business.

But, while increasing posts in this way, more than one person cannot be increased for every ten thousand rupees' daily transaction. In an event of a decline in monthly transaction,

increased posts get nullified automatically.

11. Physical Infrastructure of Hospital Pharmacy:

- (1) In order to operate the pharmacy, the Hospital must provision for a medicine dispensing room and an adequate space for storage to comply with the Codes on Sales and Distribution of Drugs, 2071.
- (2) The medicine dispensing room must be free from dampness, away from a direct sunlight, and adequately ventilated. Storage must be done according to the temperature prescribed on a medicine/medicinal substance's label.
- (3) A location for operating the pharmacy must be easily visible to general public, and as far as possible, must be at the front of the Hospital. As required, more than one pharmacy may be operated in the Hospital.
- (4) It must be with appropriately organized space for patient counselling.
- (5) A separate storage inaccessible to unauthorized person must be managed for safe keeping of a medicine and medicinal material that are no longer suitable or need to be returned or have expired, or need to be destroyed.
- (6) An appropriate staff and space for the receipt of prescription, dispensing and the collection of payment must be provisioned.
- (7) The recording of inventory and consumption, invoicing of a medicine and medicinal material must be carried out through a computer with an appropriate software containing drug information, label, information related to side effects of medicines, etc.
- (8) A list of medicines and medicinal materials provided by the Government of Nepal for free must be kept visible to everyone.
- (9) An additional aspect of the hospital pharmacy operation shall be according to the Codes on Sales and Distribution of Drugs, 2071, and Guideline for Health Institution Establishment, Operation & Upgradation Standard, 2070.
- (10) Drugs that are provided by the Hospitals for free and the rest of the drugs must be clearly segregated in the pharmacy.
- (11) Any activity pertaining to the commercial promotion of a drug cannot be conducted within the Hospital premises.

However, with the approval from the Committee, there shall be no objection to conduct a meeting or conference with a group participation, for a scientific presentation on a drug.

12. Provision of Seed Money:

- (1) The Ministry may provide seed money for the operation of the hospital pharmacy.
- (2) If the Ministry sees fit, the amount provided under Sub-section (1) may be converted into a grant.

13. Regarding Drug Distributed for Free:

- (1) A drug that has been identified to be distributed for free by the Government of Nepal must be provided for free by the hospital pharmacy.

- (2) A medicine and medicinal substance and material to be distributed for free must be procured as required through the grant money provided by the Ministry or a fund received for the procurement of a drug. For other Hospitals under the Department of Health Services, they will be made available through a procurement by the department, regional health directorates and district health/public health offices.
- (3) During a situation when the stock of a drug to be distributed for free is not available for some reason, the pharmacy is not obligated to provide such a drug for free.

However, the pharmacy must provide information regarding the unavailability of a medicine and medicinal material that are to be distributed for free on the prescription of a concerned patient.

- (4) Government hospitals must arrange for free drugs for a very poor and helpless patient even when the inventory of drugs that are to be distributed for free is not available and must make a record containing the details of patients receiving such a service public on a monthly basis.

14. Distribution of Drug Received for Free:

- (1) All Hospitals must provide for free the medicines and medicinal materials received for free from any source or as a bonus from any company.
- (2) When receiving medicines and medicinal materials for free, medicines may be received as a donation or gift based on drugs listed in the Hospital Formulary. In addition, this must be done according to the standard prescribed by the Department of Drug Administration or that determined by World Health Organisation on receiving a drug as a donation or gift.

15. Financial Management:

- (1) The hospital pharmacy shall have a separate account.
- (2) The account under Sub-section (1) shall be operated by co-signatures of the Hospital Chief or the personnel appointed by him/her and Chief Accountant.
- (3) The account under Sub-section (1) shall deposit the following funds:
 - (a) Money received from the Ministry
 - (b) Money received from daily sales
 - (c) Money received from a local body
- (4) Without a recommendation and decision from the Pharmacy Operation Committee, the funds available in the account under Sub-section (1) shall not be used for any other purpose.
- (5) Money from a daily transaction must be deposited in the bank either on the same day or by noon on the following day.
- (6) A salary, allowance and related expenses of a contracted staff working in the pharmacy must only be borne from the account under Sub-section (1).
- (7) At least ten percent of the total revenue from the sales of drugs must be deposited to the main account of the Hospital on a monthly basis.

16. Accounting of Income and Expenditure:

- (1) The accounting of income and expenditure of the pharmacy shall be done within a month after the end of every fiscal year.
- (2) While accounting for income and expenditure, ninety percent of the profit must be deposited in the main account of the Hospital.
- (3) An internal auditing must be completed within three months from the end of a fiscal year.
- (4) The auditing of the hospital pharmacy shall be conducted by the Office of the Auditor General.
- (5) At the end of each fiscal year, a trial balance of updated procured quantity, sold quantity and balance quantity in the pharmacy must be prepared.

17. No Recommendation of Specific Brand: Unless absolutely necessary, a patient must not be recommended a specific brand.

18. Submitting Report after Monitoring and Evaluation: Regarding the situation of a pharmacy operation in the Hospital, and to operate this service effectively, the Ministry, department under the Ministry, regional health directorate and district health/public health offices must carry out monitoring and evaluation every four months, and send its report to the quality assurance section of the Ministry.

19. Provision Related to Hospital Formulary: The Hospital must make the following arrangement in the Hospital Formulary:

- (A) A list of medicines and medicinal substances and materials and medicine's dosage form necessary for the Hospital according to the nature of patients' diseases must be kept updated in the Hospital Formulary.
- (B) In the Hospital Formulary, there must at least be information regarding a list of drugs, a drug's dosage, dosage form and strength, as well as an instruction regarding the storage. As additional information, the drug's indications or contraindications, adverse effects, precautions to be followed when taking the drug, the drug's comparative prices, and other details must be included.
- (C) Until the Hospital Formulary is ready, the work must be done by preparing a list of medicines and medicinal materials and substances.
- (D) Drugs included in the national list of essential medicines must be given a priority in the Hospital Formulary.

20. Special Arrangement for Private Hospital:

- (1) Private, co-operative, community, teaching as well as non-governmental sector hospitals in operation with an approval from the Government of Nepal must also operate their own pharmacy service according to this guideline.
- (2) According to the existing criteria, for ten percent of total patients who come to a hospital, the hospital under Sub-section (1) must provide free drug and service to a poor and helpless patient.

21. Software Related to Pharmacy Operation: Every hospital pharmacy must use software as directed by the Ministry to ensure uniformity. Rational use and documentation of antimicrobial and narcotic drugs shall be ensured in the software.
22. Direction May be Given: For hospitals other than those mentioned in the guideline, the Ministry may provide relevant directions on opportune pharmacy operation and it shall be the duty of the concerned hospital to follow them.
23. According to the Existing Law: A subject not mentioned in this guideline shall be as written in the existing law.
24. Repeal and Saving:
 - (1) Hospital Pharmacy Service Guideline, 2070 is hereby repealed.
 - (2) Work performed under the Hospital Pharmacy Service Guideline, 2070, is now deemed to have been performed under this guideline.