Contents

Preface

vii 1

20

1. Introduction

- I. New Dimensions of Pharmacy Practice 1
 - A. The underlying philosophy and the scope of pharmacy practice 3
 - B. The pharmacist as a member of the healthcare team 3
 - C. Clinical pharmacy 5
 - D. Pharmacovigilance 5
- II. Good Pharmacy Practice Requirements 6
 - A. The pharmacy practice activity classification 6
 - B. Quality assurance of pharmacy services 7
 - C. The six domains of healthcare quality 8
 - D. Good pharmacy practice indicators 8
 - E. Clinical Pharmacy's key performance indicators (KPIs) 9
- III. Information Management and the Use of Evidence 10
 - A. Sources of medicines information 11
 - B. Evaluation of the medical literature 15
 - C. Adherence to treatment and the patient's viewpoint 17

2. Good Dispensing Practices

- I. Dispensing Cycle 20
 - A. Dispensing procedures 20
 - B. Problems and issues in dispensing 23
 - C. Labels 24
 - D. Dispensing containers 25
- II. Medication System 25
 - A. Unit-dose medication system 25B. Controlled dosage system 26
- III. Patient Counseling and Education 26
- IV. Dispensing in Special Situations 28
 - A. Children 29
 - B. Elderly 30
 - C. Pregnancy and lactation 31
 - D. Psychiatry disorders 32
- V. Dispensing of Schedule H1 Drugs 32
- VI. Narcotic and Psychotropic Drugs (NDPs) 33
 - A. Dispensing Essential Narcotic Drugs (ENDs) 33
 - B. Preparation of ENDs against a prescription and recording of details 35
 - C. Delivery to inpatients/wards/floors 36
 - D. Pharmacist: In-charge of ENDs responsibilities 37

Pharmacy Management: Standard Operating Procedures

- VII. Conditions of Pharmacy Premises and storage of medicines in pharmacy 38
 - A. Responsibilities of the pharmacist 38
 - B. Size, layout and organization of pharmacy 39
 - C. Policies and procedures 40
 - D. Storage of medicines in pharmacy 40
 - E. Expiry dates management 41
 - F. Personal hygiene 41
 - G. Reuse/Returned medications 41
- VIII. Recalls 42
 - A. Level of recall 42
 - B. Types of recall 42
 - C. Basic information required 43
 - D. Role of pharmacists during recall 43

3. Safety in Dispensing Procedures

- I. Definitions 44
- II. Case Studies 44
- III. Dispensing Errors: Who is At Most Risk 45
 - A. Patients receiving look-alike, sound-alike (LASA) drugs 45
 - B. Use of abbreviations, symbols and dose designations 46
 - C. Patients receiving high-alert medications 48
 - D. Patients receiving high-risk medicines 49
- IV. Safe Practice Recommendations and Role of Pharmacist in Preventing Errors 50
- V. Policy for Verbal/Telephone Orders 52

4. Adverse Drug Reaction Reporting

- I. Definitions 54
- II. Classification of ADRs 54
 - A. Based on types of ADRs 54
 - B. Based on duration 56
 - C. Based on incidence (frequency of occurrence) 56
- III. Severity Assessment of ADRs 56
- IV. Casuality Assessment of ADRs 56
- V. Factors Contributing to ADRs 57
- VI. Prevention and Dealing with ADRs 57
- VII. Reporting of ADRs 58

5. Pharmaceutical Supply Management

- I. Hospital Formulary 61
- II. Definitions 62
- III. Developing Hospital Formulary 63
- IV. Formulary System Maintenance: Adding and Deleting Drugs 66 A. Medication review process 66
 - B. Evaluations of applications to add new medicines to the formulary list 67
- V. Managing Non-Formulary Drugs or Non-Listed Requests 69
- VI. Responsibilities of a Pharmacist 69

6. Procurement

- I. General 70
- II. Efficient Transparent Management 71
- III. Selection of Pharmaceuticals 71

70

61

54

44

		Contents	xi
VI. VII. VIII. IX. X. XI. XII.	Supplier Selection and Quality Assurance 72 Determining the Tender Format and General Instructions 72 Technical Specifications and Specific Instructions to Bidders 74 Conditions of Contract 76 Financing and Competition 79 Supply Order 80 Placing an Order 80 Purchases and Issue 81 Issuing Supplies 82 Documentation, Recordkeeping and Accounting 82		
7. Sup	oply Chain Management and Distribution of Pharmaceuticals		83
11. 111.	 Managing Supply Chain 83 A. Distribution cycle 83 B. Distribution sequence 83 Evaluating the Existing System 84 A. Distribution network 84 B. Storage (each facility) 85 Designing a Distribution and Storage System 85 A. Establish a distribution network 85 B. Location of the medical store 89 C. Site of medical stores 90 D. Push and pull systems 90 E. Transport 93 F. Delivery schedules 93 G. Communication 93 Distribution of Pharmaceuticals/Supply Chain in the Hospital 94 A. Functions of the store-in-charge/pharmacist include 94 B. Distribution of pharmaceuticals to wards/floors 94 C. Transport and deliveries to other health facilities 95 D. Transporting drugs safely 96 		
8. Qu	antification of Medical Supplies		97
III. IV. VI. VII. VIII. IX. X.	Why Quantify?97Action Planning98The Quantification Process98A. Preparatory phase98B. Quantification phase99Quantification Methods100Details of Consumption Method101Quantification of Drugs Calculation Sheet104		

9. Medical Stores Management

- I. Receiving and Arranging Commodities 116
 - A. Receiving health commodities 116
 - B. Arranging commodities 118

116

xii Pharmacy Management: Standard Operating Procedures

- II. Monitoring Product Quality 120
 - A. Indicators of quality problems 120
 - B. Handling complaints about product quality 121
 - C. Guidelines for sending samples for quality assurance testing 122
 - D. Preventing damaging and contamination 124
- III. Routine Warehouse or Store-room Management Tasks 124
- IV. Environment Control 126
 - A. Common terms used for storage conditions 128
 - B. Cold storage of pharmaceuticals and vaccines 129
 - C. Storage principles for thermolabile products 130
 - D. Types of refrigerators and freezers 132
 - E. Storage principles for vaccines 134
 - F. Testing/aids for checking appropriate storage 137
 - G. Vaccine stock management 138
 - H. Vaccine and diluent storage location and positioning 139
 - I. Vaccine packaging 140
 - J. Vaccine labelling 140
 - K. Temperature monitoring 141
 - L. Vaccine storage troubleshooting 142
 - M. Maintenance of the refrigerator 143
 - N. Temperature maintenance during transport 144
- V. Access Controlled Storage 146
- VI. Medical Gases: Special Considerations/Precautions for Cylinder Storage 147
- VII. Storage and Handling of Dangerous/ Hazardous Material 148
 - A. General principles of storage 148
 - B. Preventing leakage of dangerous materials/substances 149
 - C. Monitoring of dangerous materials 149
- VIII. Handling of Hazardous Drugs (HDs) 150
 - A. Facilities and engineering controls 151
 - B. Policy for handling of HDs 152
 - C. Receipt of HDs 152
 - D. Transport of HDs 153
 - E. Compounding and handling nonsterile HD dosage forms 154
 - F. HD preparation area 154
 - G. HD administration 155
 - H. HD spill management 155

10. Inventory Management

- I. Standard List of Stock Items 158
- II. Stock Records 159
- III. Selective Inventory Control Methods 160
- IV. Service Level and Safety Stock Requirements 162
- V. Physical Inventory 163
- VI. Stock Rotation and Control 165
- VII. Orderly Arrangement of Medicines 166
- VIII. Activity Reports and Performance Monitoring 168
- IX. Management Information System (MIS) In Drug Management 168
 - A. Benefits and limitations of MIS 169
 - B. Key steps in the computerization process 169
 - C. Features of procurement and inventory management software 169
 - D. The outpatient pharmacy management software 170

158

		Contents	xiii
11.	Handling of Narcotics and Psychotropic Drugs		172
	 A. Guidelines for dealing with Essential Narcotic Drugs (ENDs) 172 B. Purchase of ENDs 172 C. Storage and Records 173 D. Prescription of Narcotic Drugs 173 E. Responsibility of Pharmacist 173 F. ENDs Stock Register Requirements 174 G. Errors in Entries in the ENDs Record Book 174 H. Managing Stocks of ENDs 175 I. Golden Rules for SOPs 175 J. Managing Routine Overage or Underage for Liquid ENDs 176 K. Missing ENDs and Keys 176 L. Recording Breakage and Wastage of ENDs 176 M. Transport ENDs 177 N. Transfer of Wards 177 O. ENDs Brought in by Patients 1777 P. Disposal of ENDs 178 Q. Management of ENDs Spillages and Part Used Doses 179 		
1 2 .	Security and Protection of Stores		181
	 I. Security of Stores 181 A. Protect equipment 181 B. Secure the staff and customers 181 C. Secure pharmaceuticals 181 D. Theft prevention and control 182 II. Protecting Against Fire 182 III. Protecting Against Pests 184 		
13.	Handling of Expired or Damaged Stock, and their Safe Disposal		186
	 I. Types of Waste and their Disposal Method 186 II. Handling of Products Declared as Not-of-Standard-Quality (NSQ) 186 III. Safe Disposal and Destruction 187 IV. Disposal Methods 188 		
14.	Setting up a Medical Store/Warehouse		191
	 I. Constructing a Medical Store 191 II. Designing a Medical Store 192 III. Materials Handling Equipment And Storage Media 195 		
15.	Quality Tools in Pharmacy and Medical Stores		197
	 A. Introduction to Quality 197 B. Lean Six Sigma (LSS) terminology 198 C. 5s in Pharmacy 199 D. Using Lean Six Sigma (LSS) in Pharmacy 201 E. Example of Quality Improvement Initiatives 202 		

xiv Pharmacy Management: Standard Operating Procedures

FURTHER READING	204
APPENDIX 1a: Key Indian Regulations and Guidelines	205
APPENDIX 1b: Drugs and Cosmetic Act, 1940 Schedules	206
APPENDIX 1c: Definition of sub-standard Drugs	207
APPENDIX 2: Discrepancy report	208
APPENDIX 3: Receiving report	209
APPENDIX 4: Sample Register	210
APPENDIX 5: Sample Requisition/Issue Voucher	211
APPENDIX 6:Sample Bin/Stock Card	212
APPENDIX 7: Delivery Voucher	213
APPENDIX 8: Sample Register of Requisitions	214
Index	215