

TABLE OF CONTENTS

Book 2

Preface	i
Editorial Board	ii
Book 2 Panel	iii
Continuing Education and Program Evaluation Instructions	viii
Roles of ACCP and BPS	xi

Health Care Stakeholders I

ACCREDITATION AGENCIES—INFLUENCE ON DRUG USE AND PHARMACY QUALITY

Learning Objectives	1
Overview	1
Accreditation	1
Value of Accreditation	2
Quality	2
History of Health Care Organization Accreditation and Quality Efforts	4
American College of Surgeons	4
Joint Commission on Accreditation of Healthcare Organizations	5
American Osteopathic Association	5
Centers for Medicare and Medicaid Services	5
Commission on Accreditation of Rehabilitation Facilities	5
Accreditation Association for Ambulatory Health Care	6
National Committee for Quality Assurance	6
Key Articles	6
Agency for Healthcare Research and Quality	6
The URAC	6

Foundation for Accountability	6
Collaboratives	7
Hospital Accreditation	7
Managed Care Accreditation	7
Influence of JCAHO on the Quality of Pharmacy Services	7
The JCAHO Accreditation Program	7
The JCAHO Standards	8
The JCAHO ORYX and Core Measures	9
National Patient Safety Goals	10
Sentinel Event and Root Cause Analysis	12
Failure Mode Effect and Critical Analysis	12
Networks and Preferred Provider Organizations	12
The NCQA Influence on the Quality of Pharmacy Services	13
The NCQA Accreditation	13
Utilization Management Standards	14
Quality Management Standards	16
The HEDIS	16
Quality Compass, Health Plan Report Cards, and Quality Profiles	17
Comparison with JCAHO	17
Influence of Other Standard-setting Organizations	18
Consumer-oriented Organizations	18
Employer Groups and Coalitions	18
National Quality Forum	19
Institute of Medicine	19
Other Organizations	20
Conclusion	20
Annotated Bibliography	20
Self-Assessment Questions	23

THE GOVERNMENT AND REGULATORY AUTHORITIES

Learning Objectives	29
Introduction	29
Drug Approval Process: A Brief History	29
The FDA Rule-making Process	30
Selected FDA Updates in Research	30

Determinants of Drug Costs	73	Individuals	102
Cost of Goods Sold and Relation to Gross Margin	74	Profile	102
Research and Development Costs	74	Health Insurance Options	102
Sales and Marketing Costs	74	Individual Example—Ma & Pa Pizza	102
Comparing R&D Costs to Promotional Costs	76	Employer Demand	103
Profit Margin	76	Quality and Safety	103
Ethical and Responsible Balance	76	National Committee for Quality Assurance and	
Drug Pricing and Drug Utilization Outside the		Health Plan Employer Data and Information Set	103
United States	78	Joint Commission on Accreditation of Healthcare	
Drug Pricing	79	Organizations	108
The United States Compared to Other Countries	79	The Leapfrog Group	108
Tools Commonly Used Outside of the United		The Purchasers' Quality and Safety Techniques	109
States to Manage Pharmaceutical Budget	80	International Organization for Standardization	
International Comparisons of Drug Price	80	Certification	109
Positive and Negative Drug Lists	80	Six Sigma	111
Generic Drugs	80	Kaizen	114
Therapeutic Reference-based Pricing	80	Access and Member Satisfaction	115
Determining Added Value of New Therapies	81	Consumer Assessment of Health Plans Study	115
Physician Drug Budgets	81	Flexibility	116
Consumer Cost-sharing	81	Rising Cost of Providing Health Care Coverage	117
Industry Risk Sharing	81	Quality Purchasing Matrix	117
Pros and Cons of Direct and Indirect Drug Price		Exploring Benefit Redesign	119
Controls	82	Employee Contributions	119
Drug Promotional Activities	82	Carve-outs	120
The United States Compared to New Zealand	82	Pharmacy	120
Other Countries	83	Injectables/Infusibles	121
World Wide Web	83	Mental Health	121
Impact on Pharmacy Practice	84	Consumer-driven Health Care	122
The Role of the Pharmacists	84	Value Purchasing	122
Counterdetailing	84	Business Coalitions and Health Councils	123
Hospital Pharmacists	85	National	123
Managed Care Pharmacists	85	Local	124
Employer Group-based Pharmacists	86	Expansion of Pharmacy Practice with Benefit	
Community Pharmacist	86	Design	124
Drug Samples and Drug Vouchers	86	Current Scenarios	124
Formulary and Drug Contracting	87	Opportunity	125
Controlling Industry-Health System Interactions	87	Unmet Needs	125
Drug Contracting	87	Satisfying Employer Demand in Pharmacy Practice	126
Pharmacy Benefit Manager Role in Drug		Quality, Safety, Flexibility, and Value	126
Contracting	88	Conclusion	128
Conclusion	89	Annotated Bibliography	128
Annotated Bibliography	89	Self-Assessment Questions	131
Self-Assessment Questions	91		

EMPLOYER INFLUENCE ON BENEFIT DESIGN

Learning Objectives	97
Introduction	97
Characteristics of Employer Groups	98
Large Group	99
Profile	99
Health Insurance Options	100
Large Group Example—The Big Spender	100
Small Group	101
Profile	101
Health Insurance Options	101
Small Group Example—Freshly Squeezed	102

Health Care Stakeholders II

MEDICATION SAFETY

Learning Objectives	139
Introduction	139
Historical Context	140
Deficiencies in Medication Safety	141
Medication Safety and Quality of Care	141
Overall Impact of ADE	142
Adverse Drug Event-related Societal and	
Financial Costs	142
Frequency and Nature of Patient Harm	143

Ambulatory and Community Setting	143	Systematic Methods for Internal ADE and Error	
Long-term Care Facilities	143	Detection	168
Hospitalized Patients	143	Medical Record Review	168
Frequency of Deficiencies and Errors in Major		Adverse Drug Events and Error Finding Through	
Medication Use Process Steps	144	Drug Use and Laboratory Triggers	169
Drug History and Patient Assessment	144	Observation Technique	169
Drug Prescribing and Monitoring of		Practitioner Interventions	169
Drug Therapy	144	Technology-based Error and ADE Detection	170
Documenting and Transcribing	145	Focused Monitoring	170
Drug Preparation and Dispensing	145	Evaluating Medication Safety Processes Through	
Drug Administration by Health Care Providers	145	Comparison with “Best Practices”	170
Patient Compliance and Communication		External Error Reporting Programs	171
Deficiencies	145	Health Care System Stakeholders and Medication	
High-alert and Problem-prone Drugs	146	Safety	172
Medication Use System Factors Contributing		Public-at-large, Patients, Families, and Patient	
to Preventable ADEs	146	Advocacy Groups	172
How and When do Process Errors and		Health Care Organization and Providers	172
Deficiencies in Care Produce Patient Harm?	147	The Role of the Pharmacist	172
Why do Errors Occur?	149	Health Care Accreditation Bodies	172
Human Performance Factors Leading to Errors	150	Governmental Role in Medication Safety	172
Improving Medication Safety	152	The Pharmaceutical Industry	173
The Systems Approach to Medication Safety	152	Professional and Other Health Care Industry	
Leadership for Safety and Quality	153	Organizations	173
Developing a Culture of Safety and Quality	153	Health Care Payers and Purchasers	174
Safe Medication Use System Processes	154	Challenges and Opportunities	174
General Systems Safety Strategies and Design		Summary	174
Principles	154	Annotated Bibliography	175
Specific Medication Use Processes Safety		Self-Assessment Questions	177
Strategies and Best Practice			
Recommendations	154		
Leadership	156		
Information Availability, Transfer, and Use	156		
Drug Standardization, Task Simplification,			
and Control	156		
Improving Identification, Verification, Checking,			
Reconciliation, Warnings, and Alerts	160		
Communication and Teamwork	160		
Staffing and Competency	160		
Environment and Equipment	161		
Monitoring of Safety	161		
Patient Involvement	161		
Technologies to Improve Medication Safety	161		
Medication Safety Process Implementati			
on Strategies	162		
Reporting, Assessing, Monitoring, and Measuring	162		
Internal Drug Error Reporting	163		
Internal Error Reporting Processes and			
Mechanisms	163		
Patient Disclosure of Errors	164		
Promoting Caregiver Reporting of Drug Errors			
and Safety Deficiencies	165		
Just and Nonpunitive Responses to Drug Errors	165		
Assessing Internal Drug Error and Safety			
Deficiency Reports	166		
Evaluating Error Reports	166		
Use of External Drug Error Reports	168		

OUR PATIENTS

Learning Objectives	181
Introduction and Background	181
Trends that will Affect Patient Populations of	
the Future	182
Drug Trends	182
Patient Demographics and Attitudes	183
Generations	183
Culture	184
Age	185
Insurance Coverage	185
Patient Concerns	186
Patients’ Perceived Role of Pharmacists	186
Communication Channels	187
Health Priorities	188
Understanding Patient Behavior	189
Individual Behavior	189
Health Belief Model	189
Locus of Control	190
Protection Motivation Theory	190
Behavioral Intention Models	190
Social Cognitive and Social Learning Theories	190
Health Services Utilization Models	190
Population Behavior	190
Diffusion of Innovations and the Tipping	
Point Principle	191
What Will be the Innovations?	191

At What Time Will the Tipping Point be Reached?	192	Actions and Recommendations	215
Patient Decision-making Processes	192	Preaccreditation	215
Cognitive Psychology Theory	193	Degree Program Expansion	215
Persuasion	193	Current Status of Pharmacy Education	216
Information Overload	193	Pharmacy Continuing Education Providers	216
Attitude Formation and Attitude Strength	193	Definition of Pharmacy Continuing Education	216
Decision-making Theory	193	Relicensure Requirement	216
Choice Processes: Compensatory Versus Noncompensatory	193	Effectiveness of Continuing Education	217
Agency Theory	194	Accreditation Standards	217
Adaptive Decision Behavior; Effort-Accuracy Framework	194	Evaluation Process	218
Hierarchy of Effects and Involvement	194	Pharmacist Learning Assistance Network	219
Examples of Patient Decision-making in the Pharmacy Domain	195	New Educational Opportunities and Challenges for ACPE	220
Pharmacy Patronage	195	Distance Education	220
Patient Evaluation of Services	195	Pharmacy Technician Education and Training	220
Prescription Drug Advertising Directly to the Consumer	195	Continuing Professional Development for Pharmacists	221
Summary	196	Conclusion	222
Models of Patient Care	197	Annotated Bibliography	222
Decision-making Models	197	Self-Assessment Questions	225
Relationship Models	198		
Therapeutic Alliance	198	PAYMENT FOR CARE	
Relationship Quality	198	Learning Objectives	229
Client-centered Model	198	Introduction	229
Concordance Model	198	Historical Perspective	229
Practice Models	198	Early Development of the United States Health Care System	229
Patient as Unit of Analysis Model	198	Pre-1930: Out-of-pocket Payment for Health Services	229
Dispense First Model	199	The Great Depression and the Advent of First Major Payment Systems	230
A Mixed-model Approach	199	The Era of Expansion	230
Information Models	200	World War II	230
Health Literacy	200	The 1960s: The Era of Social Entitlement	231
Information Prescription	200	The Era of Cost-containment	232
Summary	200	Today: Three Major Payment Systems	232
Annotated Bibliography	201	The Prescription Drug Benefit	232
Self-Assessment Questions	203	Private Sector	233
		Managed Prescription Drug Benefits	233
ASSURING AN EDUCATED WORKFORCE		Public Sector—Active Military and Veterans	234
Learning Objectives	207	Active-Duty Military Personnel and Families	234
Introduction	207	Department of Veterans Affairs	235
Pharmacist Credentials	207	Medicaid and Medicare	236
Historical Perspective	207	Centers for Medicare and Medicaid Services	236
Licensure	208	Medicaid	236
Postlicensure Professional Development	208	Eligibility	237
Relative Contribution of ACPE	209	State Children’s Health Insurance Program	237
Accreditation of Pharmacy Education	210	Benefits	238
The Mission of ACPE	210	Payment to Providers	238
Organization	210	Medicaid and Prescription Drugs	238
Pharmacy Degree Programs	212	Generic Substitution	239
Evolution of Standards 2000	212	Formularies	239
Accreditation Process	214	Caps and Cost-sharing	239
Self-study Report	214	Drug Use Review	239
Evaluation Team	214	Reducing Pharmacy Reimbursement	239
On-site Evaluation	215	Medicare	239

Eligibility240
Benefits240
Medicare + Choice240
Financing241
Medicare and Prescription Drugs241
An Outpatient Prescription Drug Benefit242
Payment to Providers243
Pharmacies and Pharmacists as Medicare Providers243
Expanded Provider Status for Pharmacists244
Payment Challenges for Pharmacists244
Average Wholesale Price Erosion244
Payment for Medication Therapy Management Services244
Cost-containment245
A Medicare Outpatient Drug Benefit245
Provider Status for Pharmacists245
Role and Response245
“Get Big and Get Small”245
Create New Revenue Streams245
Unbundle the Current Payment Structure246
Conclusion246
Annotated Bibliography246
Self-Assessment Questions249