Contents

Section A
Guide to the MPJE® ...................................................... 1
    Applying for and Taking the MPJE® ......................... 1
    Content of the MPJE® .............................................. 3
    MPJE® Competency Statements ......................... 3
    Common Errors Made By Candidates .......... 10

Section B
Sources of Laws, Rules and Regulations ...................... 11
    Introduction .............................................. 11
    Pure Food and Drug Act of 1906 .................... 11
    Food, Drug and Cosmetic Act of 1938 ............... 11
    Durham-Humphrey Amendment of 1951 .......... 12
    Kefauver-Harris Amendment of 1962 .......... 13
    Medical Device Amendment of 1976 ......... 14
    Orphan Drug Act of 1983 ..................... 14
    Drug Price Competition and Patent-Term
        Restoration Act ....................................... 14
    Prescription Drug Marketing Act of 1987 .......... 15
    FDA Modernization Act of 1997 .............. 15
    Medicare Prescription Drug Improvement, and
        Modernization Act of 2003 ................... 16
    Patient Protection and Affordable Care Act
        (Health Care Reform Act) of 2010 ........ 16
    Time lines for implementation of the Patient
        Protection and Affordable Care Act of 2010: 17
    Official Compendia of the United States ........ 21
    Drugs@FDA .............................................. 22

Section C
Acronyms and Definitions ....................................... 23
    Acronyms .............................................. 23
Definitions............................................................. 29
Sample Questions ................................................. 31

Section D

Medicare and Medicaid........................................... 33
Medicare Prescription Drug Improvement and
  Modernization Act of 2003 ................................. 33
Medicare Part D ................................................... 34
Formulary Requirements........................................ 37
Prescriptions Access at “out-of-network”
  Pharmacies.......................................................... 39
Medicare Enrollment.............................................. 39
Medigap............................................................... 40
The Medication Therapy Management (MTM)
  Program............................................................... 40
Sample Questions ................................................ 43

Section E

Bringing New Drugs to Market .............................. 47
Investigational New Drug Application (IND) .... 47
Clinical Trials ...................................................... 47
Treatment Investigational New Drugs............... 48
The New Drug Application (NDA) Process ........ 49
FDA Expedited Review Programs....................... 50
Abbreviated New Drug Application (ANDA) .... 51
Supplemental New Drug Application (SNDA).... 52
FDA Classification System for New Drugs ...... 53
Therapeutic Classification .................................. 53
Chemical Classification ...................................... 54
Orphan Drugs...................................................... 55
Vaccines for Children Program (VCP) ............... 56
Sample Questions .................................................. 56

Section F

Requirements for Marketed Drug Products............ 59
   Naming New Drugs.............................................. 59
   Patent Protection.............................................. 60
   National Drug Code (NDC)................................. 61
   Good Manufacturing Practice (GMP) .................... 62
   Bad Advertising ............................................... 62
   Question ....................................................... 63
   Adulteration versus Misbranding of Products ....... 63
   Product Labeling ............................................. 65
   Labeling Requirements for Manufacturer’s
      Containers .................................................... 66
   Inactive Ingredients on Labels.......................... 67
   Special Label Warning Requirements ................. 67
   Package Inserts............................................... 69
   Identification of Commercial Solid Dosage Forms 71
   Prescription Drug Marketing Act 1987 ............... 71
   Sample Questions ............................................ 73
   Pregnancy Warnings ........................................ 77
   Risk Evaluation and Mitigation Strategies
      (REMS™) .................................................... 78
   Off-label Uses of Drugs .................................... 86
   Unit-dose Packaging and Labeling ..................... 87
   Customized Patient Med Paks ............................ 89
   The MedWatch Program ..................................... 89
   Other Product Reporting Initiatives .................... 92
   Drug Recalls .................................................. 93
   Prescription Compounding vs. Manufacturing ....... 94
   2013 Drug Quality and Security Act .................... 95
   Expiration Dating for Compounded Prescriptions 96
Compounding of Sterile Products for Use in the Home .............................................. 97
Sample Questions ......................................................... 98

Section G

Filling and Dispensing Prescriptions ............... 103
  Federal vs. State Regulations .......................... 103
  Authorization to Prescribe .......................... 104
  Health Professionals That Self-Prescribe ....... 104
  Pharmacist’s Obligation to Fill a Prescription ... 104
  Prescription Refills ...................................... 105
  Prescription Ownership ............................... 105
  Prescription File Storage Period ................. 106
  Prescription Container Labeling ................. 106
  Tall Man Lettering ...................................... 108
  Expiration Dating vs. Beyond-Use Dating ...... 108
  Sample Calculation ..................................... 110
  Sample Questions ...................................... 117
  Patient Package Inserts (PPIs) ................... 120
  Medication Guides (MedGuides) .................. 120
  Drug Product Substitution ......................... 123
  Narrow Therapeutic Index Drugs (NTIs) ...... 131
  Using the Orange Book ............................... 132
  Sample Questions ...................................... 136
  Generic Substitution of Biosimilars ............. 136
  [Biologics Price Competition and Innovation Act (BPCIA) of 2009] ......................... 136
  Mailing of Prescription Drugs ................. 137
  Sample Questions ...................................... 139
  Health Insurance Portability & Accountability Act (HIPAA) .................................. 145
How does the HIPAA affect pharmacies? .......... 146
International Commerce Involving Drugs and Drug
  Products ......................................................... 148
Counterfeit Drugs ............................................. 149
Out-of-state and Foreign Prescriptions ................. 149
Electronic Prescribing ....................................... 151
Sample Questions ........................................... 152

Section H

Controlled Substances ........................................ 159
  Definitions Related to Controlled Substances ... 159
  Registration of Manufacturers, Distributors, and
    Dispensers .................................................. 168
  Applications for Registration ............................. 168
  Re-registration ............................................ 171
  Commercial Containers .................................. 171
  Schedule I Controlled Substances ..................... 171
  Schedule II Controlled Substances ................. 172
  Schedule III Controlled Substances ................. 174
  Schedule IV Controlled Substances ................. 177
  Schedule V Controlled Substances .................. 179
  Excluded (Exempt) Substances ......................... 181
  Purchasing or Transferring Schedule I or II
    Substances .................................................. 181
  Completing DEA Form 222 ............................... 183
  Filling Orders Written on DEA Form 222 .......... 187
  Ordering Controlled Substances Using DEA
    Form 222 .................................................. 187
  Endorsing an Order Form .............................. 189
  Unaccepted or Defective Order Forms ............... 190
  Lost or Stolen Order Forms ............................ 190
  Storage of Order Forms ................................. 191
Return of Unused Order Forms .......................... 192
Cancellation and Voiding of Order Forms ........ 192
Controlled Substance Ordering System (CSOS) 193
Compounding or Repackaging With Controlled
Substances .................................................... 198
Persons Entitled To Issue Controlled Substance
Prescriptions ................................................... 199
Purpose for Issuing of Controlled Substances
Prescriptions ................................................... 199
Practitioner Self-prescribing ............................. 200
Issuing Of Controlled Substance Prescriptions ... 201
Persons Entitled To Fill Controlled Substance
Prescriptions ................................................... 203
Electronic Prescriptions for Controlled
Substances ....................................................... 203
Detoxification or Maintenance Treatment ........ 207
Schedule II Prescription Requirements .......... 208
What Is An Emergency? ................................. 210
Missing Information ....................................... 210
Faxing of Schedule II Prescriptions ............... 211
Refilling Schedule II Prescriptions ............... 211
Partial Filling of Schedule II Prescriptions ....... 212
Labeling Schedule II Prescriptions ............... 213
Schedule III, IV, and V Prescription
Requirements ............................................... 215
Refilling of Schedule III, IV or V Prescriptions... 216
Partial Filling of Schedule III, IV, and V
Prescriptions ............................................... 220
Labeling and Filling of Schedule III, IV and V
Prescriptions ............................................... 221
Transfer of Prescription Information Between Pharmacies .................................................. 222
Dispensing Schedule V Controlled Substances
Without a Prescription ............................................. 224
Communicating prescription information between retail pharmacies and central fill pharmacies for
initial and refill prescriptions of Schedule III, IV,
or V controlled substances. ............................... 226
Disposal of Controlled Substances .................. 227
Transfer of Controlled Substances Between Pharmacies................................................. 228
Controlled Substance Records ......................... 230
Inventory Requirements ................................. 232
Verification of DEA Numbers .......................... 235
Prescribing by Hospital Employees .................... 236
Mid-level Practitioners (MLP) ....................... 237
Storage of Controlled Substances .................... 238
Pharmacy Employment Practices ................... 239
Theft of Controlled Substances ....................... 240
Federal Investigation of Pharmaceutical Theft or
Robbery ............................................................ 241
Required Records .......................................... 241
Storing Prescription Information ..................... 242
Exportation of Controlled Substances ............. 246
Methamphetamine Anti-Proliferation .......... 246
Marijuana Prescribing and Dispensing ............ 248
Sample Questions .......................................... 249

Section I

Treatment of Narcotic Dependence .................. 253
Use of Buprenorphine Products ....................... 253
Required Services for Opioid Treatment Programs
(OTPs) ................................................................. 254
Prevention of Drug Diversion ............................ 256
Naloxone For Treatment of Opium and Opioid
Overdose ................................................................. 258

Section J

Nonprescription Drugs ....................................... 259
General Labeling Requirements ........................ 259
FDA Adverse Event Reporting System
(FAERS) ................................................................. 261
OTC Labeling for Pregnancy and Nursing
Mothers ................................................................. 262
OTC Labeling of Sodium Content ...................... 263
OTC Labeling for Other Electrolytes ................. 264
Tamper-resistant Packaging Act ......................... 264
Medicaid Tamper-Resistant Prescription
Requirement ........................................................... 265
Prescription to OTC Reclassification .................. 266
Refilling Prescriptions Written for Nonprescription
Drugs ................................................................. 267
Sample Questions .................................................. 268

Section K

Dietary and Nutritional Supplements ................. 269
Dietary Supplement Health Education Act
(DSHEA) ................................................................. 269
Official Status of Herbals .................................... 271
Labeling for Herbals and Dietary Supplements ... 271
Ban on Sales of Ephedra and Ephedrine
Alkaloids ............................................................. 272
Sample Questions .................................................. 273
Homeopathic Drug Products .............................. 274