**TABLE OF CONTENTS**

PAGE

80.01DEFINITIONS 1

80.01-1Authorized Representative 1

80.01-2Brand-Name Drug 1

80.01-3Caloric Supplements/Substitutes 1

80.01-4Compound Prescription 1

80.01-5Controlled Substances 1

80.01-6Covered Drugs1

80.01-7Creditable Coverage1

80.01-8DESI1

80.01-9Dispensing Practitioner 1

80.01-10Drug Utilization Review (DUR) 1

80.01-11Drug Utilization Review Committee (DUR Committee) 1

80.01-12Food and Drug Administration Orange Book2

80.01-13Formulary 2

80.01-14Generic Drugs 2

80.01-15Legend Drug 2

80.01-16Lock-In2

80.01-17Mail Order Pharmacy2

80.01-18Maine Drugs for the Elderly Program (DEL)2

80.01-19Maine Maximum Allowable Cost (MMAC)2

80.01-20Maintenance Drugs 2

80.01-21Maximum Allowable Cost (MAC) 3

80.01-22Medical Food3

80.01-23Medicare Part D3

80.01-24Medicare Part D Excluded Drug3

80.01-25Medi-Span3

80.01-26Metropolitan Statistical Area (MSA)3

80.01-27National Drug Code (NDC)3

80.01-28New Drugs 3

80.01-29Non-Preferred Drugs3

80.01-30OBRA 90 3

80.01-31Over-ride3

80.01-32Over-The-Counter Drug (OTC) 3

80.01-33Pharmacy Provider 4

80.01-34Preferred Drugs4

80.01-35Preferred Drug List4

80.01-36Retail Pharmacy 4

80.01-37Specialty Drug4

80.01-38Specialty Drug List4

80.01-39Specialty Pharmacy4

80.01-40State Drug File4

80.01-41Telepharmacy4

80.01-42Therapeutic Category5

80.01-43 Usual and Customary Charge5

TABLE OF CONTENTS

PAGE

80.02ELIGIBILITY FOR CARE5

80.03DURATION OF CARE 5

80.04PHARMACY COMMITTEES 5

80.04-1Drug Utilization Review (DUR) Committee 5

80.04-2Formulary Committee 11

80.05COVERED SERVICES 15

80.05-1Drug Benefits 15

80.05-2Compound Prescriptions 15

80.05-3Drugs Covered for Certain Conditions/Procedures Only 16

80.05-4Drugs Obtained Through The Department’s Mail Order Pharmacies16

80.06NON-COVERED SERVICES16

80.07POLICIES AND PROCEDURES 18

80.07-1Regulation of Pricing 18

80.07-2Standards of Participation for Retail Pharmacies 18

80.07-3Standards for Mail Order Pharmacies19

80.07-4Prior Authorization (PA) 19

80.07-5Preferred Drug List (PDL)23

80.07-6Dispensing Practices 26

80.07-7Refills 27

80.07-8Pharmacist's Responsibility28

80.07-9Restriction and Narcotic Prescriber Plans28

80.07-10Program Integrity 29

80.07-11Over-Rides29

80.08CO-PAYMENT 29

80.08-1Pharmacy Benefits Provided By Retail and Specialty Pharmacy Providers30

80.08-2Pharmacy Benefits Provided By Mail Order Pharmacy Providers30

80.08-3Benefit for People Living With HIV/AIDS30

80.09REIMBURSEMENT 30

80.09-1Reimbursement Rates30

80.09-2Returned Reusable Drugs for Retail Pharmacy Provider…………………………...35

80.10BILLING INSTRUCTIONS 36

**80.01DEFINITIONS**

80.01-1**Authorized Representative** refers to the Department’s authority per 22 M.R.S.A. §§ 3174-II and LD 1325 to enroll and reenroll MaineCare members into a Medicare Part D plan, apply for Medicare Part D benefits and subsidies on their behalf, and at the Department’s discretion, file exceptions and appeals on their behalf. The Department may also identify a designee for this function.

80.01-2**Brand-Name Drug** is defined as a single-source drug, a cross-licensed drug, or an innovator drug.

80.01-3**Caloric Supplements/Substitutes** are over-the-counter products that contain fats, and/or proteins, and/or carbohydrates and are prescribed by a licensed provider for the express purpose of enhancing caloric intake to address an illness or condition, and which have a standard national drug code (NDC) number in the Medi-Span drug file database.

80.01-4**Compound Prescription** is any product for which two (2) or more ingredients are

extemporaneously mixed in usually accepted therapeutic doses. This requires the pharmacist's skill in weighing, measuring, levigating, etc., at the time of dispensing. The allowable compounding fee applies to the preparation of an individual prescription. It does not apply to prescriptions dispensed from a previously prepared stock supply (i.e., premixing a special lotion or ointment in gallons or pounds).

80.01-5**Controlled Substances** are drugs that come within the scope of the Controlled

Substances Act and are divided into five schedules- I, II, III, IV and V.

80.01-6**Covered Drugs** are drugs that are reimbursable pursuant to Section 80.05.

80.01-7**Creditable Coverage** is when the actual value of coverage equals or exceeds the actuarial value of standard Medicare prescription drug coverage, as demonstrated through the use of generally accepted actuarial principles and in accordance with CMS actuarial guidelines.

80.01-8**DESI** means the Drug Efficacy Study Implementation Program of the Food and Drug Administration (FDA).

80.01-9**Dispensing Practitioner** is a licensed practitioner who, within the scope of his or her license, prepares and dispenses medication, instructs patients to self-administer medication on a regular basis, and is located no less than fifteen (15) miles from a licensed pharmacy.

80.01-10**Drug Utilization Review (DUR)** means a process designed to ensure that prescriptions are appropriate, medically necessary and not likely to result in adverse medical results.

**Drug Utilization Review Committee (DUR Committee)** means an advisory committee to the Department of Health and Human Services for the MaineCare

80.01DEFINITIONS (cont.)

program and other State prescription benefits administered by the Office of MaineCare Services (OMS), comprised of physicians and pharmacists who are licensed to prescribe or dispense drugs in Maine. The DUR Committee conducts drug utilization review for the Department.

80.01-12**Food and Drug Administration (FDA) Orange Book,** referred to as the “Orange Book” in this Section, is the *FDA Approved Drug Products with Therapeutic Equivalence Evaluations*, which rates the therapeutic equivalence of generic drugs.

80.01-13**Formulary** is a list of medicines that includes all Legend (prescription) Drugs, to comply with OBRA 90 as amended, except those excluded by these regulations and those over-the-counter drugs listed in Section 80.05-1.

80.01-14**Generic drugs** are drugs other than those defined as brand-name drugs.

80.01-15**Legend Drug** is a drug bearing the statement "CAUTION: Federal Law Prohibits Dispensing Without A Prescription" or “Rx Only,” as allowed by the Food and Drug Administration.

80.01-16**Lock-in**, for the purpose of this Section, is when members are restricted to obtaining

all or specific prescriptions from only one provider and/or pharmacy.

80.01-17**Mail Order Pharmacy Provider** is a pharmacy provider that dispenses prescription medications by U.S. mail or private carrier. Mail order pharmacy providers must have a NABP (National Association of Boards of Pharmacy) provider number uniquely identifying the provider as a mail order pharmacy for purposes of billing. Mail order pharmacy providers must be licensed by the Maine Board of Pharmacy, enrolled as Medicare and MaineCare providers, and be operating under contract with the Department. Mail order pharmacy providers must dispense prescription medications from within the United States. Mail order pharmacy providers must process claims through the State’s electronic claims processing system to the standards required by the Department.

80.01-18**Maine Drugs for the Elderly Benefit (DEL)** provides low-cost prescription and limited over-the-counter drugs and medical supplies to certain elderly and disabled members pursuant to 22 M.R.S.A. § 254-D. The DEL Benefit, which is not a MaineCare benefit, is further described in Chapter 104, Section 2.

80.01-19**Maine Maximum Allowable Cost (MMAC)** is the maximum cost allowed by the Maine Department of Health and Human Services for certain multiple source drugs.

80.01-20**Maintenance Drugs** are drugs that are used to treat conditions that are usually chronic or long-term. Maintenance drugs include caloric supplements/substitutes, medical foods, and specialty drugs.

80.01DEFINITIONS (cont.)

80.01-21**Maximum Allowable Cost (MAC)** is the Federal Upper Limit (FUL) established by the federal government for certain prescription drugs. The MaineCare program reimbursement to a pharmacy may not exceed the MAC for any such drugs.

80.01-22**Medical Food** is a product prescribed by a licensed provider for a member with special

#### nutrient needs, in order to manage a disease or health condition, when the member is under the provider’s on-going care. The label must clearly state that the product is intended to manage a specific medical disorder or condition. An example of a medical food is a food for use by persons with phenylketonuria, i.e., foods formulated to be free of the amino acid phenylalanine.

80.01-23**Medicare Part D** means the prescription drug benefit provided under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173.

80.01-24**Medicare Part D Excluded Drugs** are those drugs not cExhibit VII-4(c)Part IIDepartment ofHousing and UrbanDevelopment24 CFR Part 35, et al.Requirements for Notification, EvaluationAnd Reduction of Lead-Based PaintHazards in Federally Owned ResidentialProperty and Housing Receiving FederalAssistance; Final RuleVII-67WAIS Document Retrieval[Code of Federal Regulations][Title 24, Voluovered by Medicare Part D pursuant to Title XIX, Section 1927, which the Department will continue to reimburse if otherwise covered under this Section.

80.01-25**Medi-Span** is a nationally recognized published drug database. The Department uses the designations in this database to create its State drug file to determine which drugs are brand-name (single-source, cross-licensed or innovator) and which drugs are generic (multiple-source) drugs for the purposes of calculating reimbursement.

80.01-26**Metropolitan Statistical Area (MSA)** is a federal standardized designation using postal zip codes to define rural areas. The Department will define rural by applying MSA/Non-MSA designation to the zip code of the member’s residence.

80.01-27**National Drug Code (NDC)** is a universal drug coding system for human drugs established by the Federal Food and Drug Administration (FDA). The FDA assigns each drug a unique identifier specifying the labeler/vendor, product, and package.

80.01-28**New Drugs** are drugs that receive a New Drug Application (NDA) from the Food and Drug Administration after November 1, 1990.

80.01-29**Non-Preferred Drugs** are covered drugs that are not preferred drugs.

80.01-30**OBRA 90** is the Omnibus Budget Reconciliation Act of 1990 as amended.

80.01-31**Over-ride** is a situation where unusual circumstances warrant the Department to authorize a pharmacy to waive a standard condition or requirement for dispensing a medication in order to process a claim.

80.01-32**Over-The-Counter Drug (OTC)** is a drug that can be purchased without a prescription.

80.01DEFINITIONS (cont.)

80.01-33**Pharmacy Provider** is, for the purposes of determining the proper reimbursement charge, a corporation, association, partnership, or individual that either provides pharmacy services pursuant to a provider agreement or is related by ownership or control to an entity that provides MaineCare pharmacy services, and also accepts Medicare assignment. This definition of provider applies only to Section 80, Pharmacy Services, in the MaineCare Benefits Manual.

80.01-34**Preferred Drugs** are covered drugs that have a lower net cost and/or advantages in clinical efficacy within a therapeutic category as determined by the Department after reviewing the recommendation of the Drug Utilization Review Committee.

80.01-35**Preferred Drug List (PDL)** is a listing of covered drugs setting forth such information as their status as preferred or non-preferred, whether prior authorization is required, step order, and any other information as determined by the Department to be helpful to members, pharmacists, prescribers and other interested parties.

80.01-364**Retail Pharmacy Provider** is a pharmacy that possesses a valid outpatient pharmacy license issued by the Board of Pharmacy, accepts Medicare assignment, and which serves MaineCare members. Out-of-state domestic retail pharmacy providers within fifteen (15) miles of the Maine/New Hampshire border are treated the same as Maine retail pharmacy providers, as provided in MaineCare Benefits Manual, Chapter I, Section 1.03.

80.01-37**Specialty Drugs** are covered drugs that, due to their high cost, short shelf life, special handling requirements and instruction, or other factors, are obtained from Specialty Pharmacy Providers. Specialty drugs are prescribed for a limited number of usually chronic conditions that generally affect a relatively small portion of the population.

##### 80.01-38**Specialty Drug List** is a list established by the Department of covered drugs consisting of certain specialty drugs that the Department has determined may be obtained through Department-approved Specialty Pharmacy Providers. The Department will post and update the Specialty Drug List on the designated website.

80.01-39**Specialty Pharmacy Providers** are those pharmacies approved by the Department to dispense specialty drugs. Specialty pharmacy providers must have a separate MaineCare provider number uniquely identifying the provider as a specialty pharmacy for purposes of billing. Specialty pharmacy providers must be approved by the Department, unless the pharmacy provider already has an approved written agreement with the Department as of April 1, 2005 to dispense growth hormones or synagis only.

80.01-40**State Drug File** is the drug file database used by the Department for the purpose of managing the pharmacy benefit.

80.01-41**Telepharmacy** is a method of delivering prescriptions dispensed by a pharmacist to a remote site. Pharmacies using telepharmacy delivery of prescriptions must follow all

80.01DEFINITIONS (cont.)

applicable State and Federal regulations and Maine State Board of Pharmacy rules, including using staff qualified to deliver prescriptions through telepharmacy.

80.01-42**Therapeutic Category** is a grouping of drugs by comparable therapeutic effect, as determined by the Department.

80.01-43**Usual & Customary Charge** is the reimbursement amount the general public is requested to pay for the goods or services provided.

**80.02ELIGIBILITY FOR CARE**

Individuals must meet the eligibility criteria as set forth in the MaineCare Eligibility Manual. Some members may have restrictions on the type and amount of services they are eligible to receive. It is the responsibility of the provider to verify eligibility and benefit level. The following members are eligible for some or all of the covered services set forth in this Section:

MaineCare members who receive full MaineCare benefits and certain members who receive special benefits are eligible to receive pharmacy benefits as described in this Section.

Members who are eligible for Medicare Part D are not eligible for MaineCare coverage of drugs covered by Medicare Part D. The Department may automatically enroll such eligible MaineCare members without creditable coverage into Medicare Part D and act as an authorized agent on their behalf. The Department will reimburse Medicare Part D Excluded Drugs for members dually eligible for Medicare Part D when those drugs are otherwise covered by MaineCare for members not eligible for Medicare Part D.

**80.03DURATION OF CARE**

Each MaineCare member is eligible for as many covered services as are medically necessary within the limits of this Section. The Department reserves the right to request additional information to evaluate medical necessity.

**80.04PHARMACY COMMITTEES**

80.04-1Drug Utilization Review (DUR) Committee

A.Purpose

The purpose of the Drug Utilization Review (DUR) Committee is to provide advice to the OMS on prescription drug utilization with the goal of assuring that prescriptions are appropriate, medically necessary, and not likely to result in adverse results. The DUR Committee is created in compliance with OBRA 90 as amended (Title XIX, Section 1927).

80.04PHARMACY COMMITTEES (cont.)

B.Membership

The Director of the OMS will appoint DUR Committee members. The Committee shall consist of at least the following members, to be composed as follows:

1.A minimum of four members shall be allopathic physicians currently

licensed and actively practicing medicine in Maine.

2.One member shall be an osteopathic physician currently licensed and actively practicing medicine in Maine.

3.Three members shall be pharmacists currently licensed and actively practicing pharmacy in Maine.

4.One member shall be either the OMS medical director or designated pharmacy physician consultant.

5.One member shall be either a hospital pharmacist who is currently licensed and actively practicing pharmacy in Maine or a pharmacist with pharmacy benefit management experience. The OMS Director may also require a hospital pharmacy background.

6.One member shall be the pharmacy benefits manager for OMS, and an assistant pharmacy benefits manager or other OMS pharm