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An Office of the
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DATE: January 1, 2013

TO: Interested Parties

FROM: Stefanie Nadeau, Director, Office of MaineCare Services

SUBJECT: Adoption Emergency Rule - MaineCare Benefits Manual, Chapter II, Section 80, Pharmacy Services

The Department of Health and Human Services (DHHS) has adopted an emergency rule to impose limits on opioid medications used for the treatment of pain, pursuant to PL 2011, ch. 657, Part O and section L-1. This emergency rule includes definitions of acute and non-acute pain, establishes certain exclusions as described in the legislation, mandates the use of a pain management care plan when a member requires the extended use of opioid medications for the treatment of pain and identifies therapeutic treatment options that must be utilized for members who are prescribed opioid medications to treat non-acute pain.

Rules and related rulemaking documents may be reviewed at, and printed from, the MaineCare Services website at http://www.maine.gov/dhhs/oms/rules/index.shtml . For a fee, interested parties may request a paper copy of rules by calling 207-287-9368. For those who are deaf or hard of hearing and have a TTY machine, the TTY number is 711.

If you have any questions regarding the policy, please contact Provider Services at 1-866-690-5585 or TTY: 711.

Notice of Agency Rule-making Adoption

AGENCY: Department of Health and Human Services, Office of MaineCare Services

CHAPTER NUMBER AND TITLE: MaineCare Benefits Manual, Chapter II, Section 80, Pharmacy Services

ADOPTED RULE NUMBER:

CONCISE SUMMARY: The Department of Health and Human Services (DHHS) has adopted an emergency rule to impose limits on opioid medications used for the treatment of pain, PL 2011, ch. 657, Part O and section L-1. This emergency rule includes definitions of acute and non-acute pain, establishes certain exclusions as described in the legislation, mandates the use of a pain management care plan when a member requires the extended use of opioid medications for the treatment of pain and identifies therapeutic treatment options that must be utilized for members who are prescribed opioid medications to treat non-acute pain.

See http://www.maine.gov/dhhs/oms/rules/index.shtml **for rules and related rulemaking documents.**

EFFECTIVE DATE: January 1, 2013

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SECTION 80	PHARMACY SERVICES	ESTABLISHED 4/1/79 LAST UPDATED ~~9/30/12~~1/1/13

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80.01 DEFINITIONS

Eff. 1/1/13 80.01-1 Acute Pain is any pain expected to be resolved within 60 days.

80.01-~~1~~2 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~~3 Brand-Name Drug is defined as a single-source drug, a cross-licensed drug, or an innovator drug.

80.01-~~3~~4 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.

80.01-~~4~~5 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~~6 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~~7 Covered Drugs are drugs that are reimbursable pursuant to Section 80.05.

80.01-~~7~~8 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~~9 DESI means the Drug Efficacy Study Implementation Program of the Food and Drug Administration (FDA).

80.01-~~9~~10 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~~11 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.

80.01-~~11~~12 Drug Utilization Review Committee (DUR Committee) means an advisory committee to the Department of Health and Human Services for the MaineCare program and other State prescription benefits administered by the Office of MaineCare Services (OMS), comprised

80.01 DEFINITIONS (cont.)

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~~13 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~~14 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~~15 Generic drugs are drugs other than those defined as brand-name drugs.

80.01-~~15~~16 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~~17 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~~18 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~~19 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~~20 Maine Maximum Allowable Cost (MMAC) is the maximum cost allowed by the Maine Department of Health and Human Services for some multiple source drugs and other non-drug covered products provided through the pharmacy point of service system (POS).

80.01-~~20~~21 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.

80.01-~~21~~22 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 DEFINITIONS (cont.)

80.01-~~22~~23 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. Medical foods are limited to formula only.

80.01-~~23~~24 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~~25 Medicare Part D Excluded Drugs are those drugs not covered 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~~26 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~~27 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~~28 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~~29 New Drugs are drugs that receive a New Drug Application (NDA) from the Food and Drug Administration after November 1, 1990.

Eff. 1/1/13 80.01-30 Non-Acute Pain is any pain that has lasted or is expected to last more than sixty (60) days and impacts and is expected to impact a member's level of function for more than 60 days.

80.01-~~29~~31 Non-Preferred Drugs are covered drugs that are not preferred drugs.

80.01-~~30~~32 OBRA 90 is the Omnibus Budget Reconciliation Act of 1990 as amended.

80.01-~~31~~33 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~~34 Over-The-Counter Drug (OTC) is a drug that can be purchased without a prescription.

Eff. 1/1/13 80.01-35 Pain Management Care Plan is a plan of care ordered by a rendering provider or consulting provider including the use of at least one therapeutic treatment option.

80.01 DEFINITIONS (cont.)

80.01-~~33~~36 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~~37 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~~38 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~~39 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~~40 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~~41 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~~42 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~~43 State Drug File is the drug file database used by the Department for the purpose of managing the pharmacy benefit.

80.01-~~41~~44 Telepharmacy is a method of delivering prescriptions dispensed by a pharmacist to a remote site. Pharmacies using telepharmacy delivery of prescriptions must follow all applicable

80.01 DEFINITIONS (cont.)

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

80.01-~~42~~45 Therapeutic Category is a grouping of drugs by comparable therapeutic effect, as determined by the Department.

Eff. 1/1/13

80.01-46 Theraputic Treatment Options include, but are~~is~~ not limited to: Physical Therapy, Chiropractic Therapy, Osteopathic Manipulative Treatment, Cognitive Behavioral Therapy and/or Acceptance and Commitment Therapy.

80.01-~~43~~47 Usual & Customary Charge is the reimbursement amount the general public is requested to pay for the goods or services provided.

80.02 ELIGIBILITY 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.

80.03 DURATION 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.

80.04 PHARMACY COMMITTEES

80.04-1 Drug 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

80.04 PHARMACY COMMITTEES (cont.)

DUR Committee is created in compliance with OBRA 90 as amended (Title XIX, Section 1927).

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 a 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 pharmacist shall have been nominated by the DUR.

7. The Department shall be represented by at least one person employed by the Department and may include the MaineCare Medical Director or MaineCare Pharmacy Director. Department representatives will be available to provide information on policy and legislative changes, and assist the Board as needed. The Department representative will support the DUR in assuring that DUR initiated policy, programmatic and system configuration changes are implemented. Department representatives are not considered voting members.

C. Method of Selection.

The Director of the OMS shall choose appointed members of the DUR Committee from lists of nominees presented by the following groups. The Director may elect not to appoint from a list if no nominee on the list is acceptable to the Director. (These lists shall contain sufficient numbers of nominees in order to allow the OMS Director flexibility in selecting a Committee with diverse membership):

1. The physicians may be nominated by the Maine Medical Association, the DUR Committee, and other state medical societies including the Nursing Home Medical Director Association.

80.04 PHARMACY COMMITTEES (cont.)

2. The osteopathic member may be nominated by the Maine Osteopathic Association, other medical societies, or the DUR Committee.

3. The pharmacists shall be nominated by the Maine Pharmacy Association or the DUR Committee.

4. The hospital pharmacist or pharmacist with pharmacy benefit management (PBM) experience shall be nominated by the Maine Society of Hospital Pharmacists or the DUR Committee.

5. The Committee may nominate candidates for ad-hoc specialty committees to offer advice on an as needed basis.

D. Terms of Appointment.

Members of the DUR Committee shall be appointed to terms as follows:

1. All physician and pharmacist members are appointed for three-year terms.

2. All vacancies shall be filled by the appointment of a person to fill the remainder of the term. Such person shall be from the same category as the person replaced.

3. No appointed person may serve more than three terms, except that appointees with initial terms of less than three years may be reappointed for three subsequent full three-year terms.

4. Except as otherwise noted, all subsequent appointments shall be for three-year terms.

5. In order to ensure the successful, uninterrupted operation of the DUR Committee, if no qualified and willing candidates are found, Committee members with expired appointments may have their term extended at the discretion of the OMS Director until such time as a suitable replacement is obtained.

E. Operation of the DUR Committee

The DUR Committee shall develop and adopt formal policies and procedures for its use. These policies shall include but not be limited to:

1. Selection of a chairperson;

2. Setting a schedule for regular meetings, (at least quarterly);

3. Setting quorum requirements;

80.04 PHARMACY COMMITTEES (cont.)

4. Publishing notices of meetings;

5. Ensuring that all DUR activities will be consistent with confidentiality requirements of the DHHS, including 42 C.F.R. 431, sub part F;

6. Establishing, as needed, regional DUR committees to assist the DUR Committee in its evaluations;

7. Establishing procedures for appeal of its decisions;

8. Preparing and disseminating its minutes;

9. Agreeing to use a consensus process to resolve differences between source materials; and

10. Providing direction for the preparation and approval of its annual report.

F. Functions and Responsibilities

The DUR Committee shall be responsible for the following duties and functions:

1. In compliance with Federal and State requirements, the DUR Committee shall determine policy, procedures, and standards for the implementation of MaineCare DUR process, the primary focus of which shall be the utilization of drugs and education of providers and members to maximize the quality of care provided. The DUR may also review drug utilization from other pharmacy benefits. The DUR will make recommendations to the Department as to which drugs require prior authorization and the prior authorization criteria for those drugs. The DUR Committee will also review new drugs for Preferred Drug List (PDL) status.

2. The DUR shall develop and maintain a working agreement with related Boards, agencies or societies, including, but not limited to: the Board of Commissioners of the Profession of Pharmacy, the Maine Board of Osteopathic Medicine, the Board of Registration in Medicine, Program Integrity staff, the Maine Medical Association, the Maine Osteopathic Association, and the staff of the Office of MaineCare Services, in order to clarify the areas of responsibility for each.

3. The DUR Committee shall develop a drug utilization review process in accordance with the following:

   a. The DUR Committee shall develop parameters in accordance with Federal guidelines to perform on-going periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross

80.04 PHARMACY COMMITTEES (cont.)

overuse or inappropriate or medically unnecessary care among physicians, pharmacists, and MaineCare members.

b. The DUR Committee shall establish standards of review based upon compendia that shall consist of at least the following:

i. American Society of Hospital Pharmacists Formulary Service;

ii. United States Pharmacopoeia Drug Information;

iii. American Medical Association Drug Evaluations; and

iv. Current peer-reviewed literature.

c. The DUR Committee shall resolve, by consensus, any discrepancies in the compendia.

4. The DUR Committee shall:

a. Submit recommendations to the OMS for policy changes for more efficient management of services,

b. Provide for on-going intervention for members, physicians, and pharmacists targeted toward therapy problems, including individuals identified in the course of drug reviews performed under this section. Such interventions shall include in the appropriate instances the following:

i. Information to physicians and pharmacists concerning the DUR Committee's duties and the profile for its standards;

ii. Written, oral, or electronic reminders concerning patient-specific or drug-specific (or both) information with suggested changes in prescribing or dispensing practices, communicated in a manner designated to ensure the privacy of member related information.

c. Use face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions;

d. Provide intensified review or monitoring of selected members, prescribers or dispensers; and

80.04 PHARMACY COMMITTEES (cont.)

e. Reevaluate interventions after an appropriate time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and to recommend modifications as necessary.

5. The DUR Committee shall:

a. Review new drugs for Preferred Drug List (PDL) status and make determinations no later than six (6) months after their entry onto the market.

b. In making a determination of PDL status, the DUR Committee shall consider whether a new drug is:

i. therapeutically equivalent or superior to existing preferred or non-preferred choices; and

ii. as safe or safer than existing preferred or non-preferred choices; and

iii. whether the net cost, adjusted for all rebates, is less expensive than all existing PDL choices.

c. The Department will designate new drug entities as follows:

i. If the FDA classifies a new medication as a priority drug, the Department may indicate that such a drug is preferred until the DUR Committee reviews the drug; or

ii. The Department may also decide to designate a new drug as "draft preferred" and provide immediate temporary access and increased therapeutic choice to physicians until the drug is reviewed; or

iii. The Department will designate new drug entities as non-preferred by default until the DUR Committee has completed the PDL review.

6. The DUR Committee shall prepare and submit a report to the OMS Director not less frequently than annually that shall include a description of the Committee's activities, including the nature and scope of the prospective and retrospective drug utilization review along with the DUR Committee's recommendations, a summary of the interventions on quality of care, and an estimate of the savings generated as result.

80.04 PHARMACY COMMITTEES (cont.)

7. Other reports and data shall be provided by the DUR Committee to the State at such time and in such format as the United States Secretary of Health and Human Services shall require from the State.

G. Confidentiality

The DUR Committee shall perform its duties in compliance with the confidentiality policies and rules of the OMS, including 42 C.F.R.b 431, sub part F and of other Maine boards of registration.

H. Independence of the DUR Committee

The DUR Committee's relationship to the OMS's Program Integrity Unit and to physician and pharmacist regulatory boards shall be as follows:

1. The DUR Committee shall not directly participate in any Program Integrity Unit fraud or abuse operation or activities except to the extent that educational materials prepared by the DUR Committee are provided to the OMS, as they are provided, members, and to the public.

2. The DUR Committee shall not involve itself as an entity in any individual cases relating to professional conduct or practice standards that may be before physicians' (MD or DO), or pharmacists' regulatory or oversight boards.

3. The DUR Committee may, however, following educational interventions and other educational assessments it may perform, refer individual matters to the OMS or to the appropriate regulatory board if in its judgment such referral is appropriate.

80.04-2 Formulary Committee

A. Purpose

The purpose of the Formulary Committee, if initiated, will be to establish a formulary for the MaineCare program to identify which prescription and over-the-counter drugs are subject to coverage under the MaineCare program in compliance with OBRA 90 as amended (Title XIX, Section 1927). The statutory authority to establish a Formulary Committee is found at 22 M.R.S.A. 3174-M.

B. Membership

The Director of OMS will appoint the Formulary Committee. The Committee shall consist of nine members, including three actively practicing pharmacists and three actively practicing physicians.

80.04 PHARMACY COMMITTEES (cont.)

At least one pharmacist shall be a clinical hospital pharmacist. At least one physician shall be a doctor who specializes in infectious diseases, one in primary care, and one in surgery. The pharmacists and physicians shall be MaineCare providers and shall serve for staggered three-year periods of time at the pleasure of the Director of the OMS.

In addition to the members outlined above, the Director of the OMS or the Director's designee, as well as the Pharmacy Unit Manager employed by the OMS, and the Director of the Maine HHS Public Health or the Director's designee shall serve on the Committee. In addition to the nine voting members outlined above, the Formulary Committee will have at least two non-voting consumer members appointed by the MaineCare Advisory Committee, who shall not be included when determining a two-thirds majority. The committee shall choose a chairperson from among the voting members. The Director of the OMS will appoint a secretary.

C. Meetings

Meetings of the Drug Formulary Committee will be held at the discretion of the Director of the OMS or the Committee chairperson upon written petition of one-third of the Committee members.

D. Approval of New Drugs

Drugs will be added to the formulary, and will be deleted from the formulary, only upon a vote of two-thirds of the Formulary Committee members present, the procedure for which is described in Section 80.04-2(E). When a new drug does not meet the two-thirds vote for approval to be added to the formulary, requests for such drugs shall be reviewed on a prior authorization (PA) basis as outlined in Section 80.07-4.

E. Formulary Policy and Procedures

1. Drugs will be considered for addition to the formulary in one of four ways:

a. By the Formulary Committee, on the basis of evidence of sufficient requests for the drug through the PA process outlined in Section 80.07-4 to justify consideration for addition to the formulary.

The OMS may also request consideration of drugs based on the volume of inquiries received.

b. The Committee may initiate consideration of over-the-counter drugs, since such drugs are not generally approved through the PA process.

80.04 PHARMACY COMMITTEES (cont.)

c. The Committee may also, through an on-going review of the formulary by therapeutic class, identify areas that are deficient or areas of possible deletion or restriction.

d. The drug manufacturer may initiate consideration of drugs for which there will be no fiscal impact as defined herein.

2. The steps to be followed for consideration by the Committee for the addition of drugs to the formulary are as follows:

a. The Department will prepare material for distribution to Committee members commenting on efficacy, therapeutic benefits, and current peer reviewed literature.

The Committee will arrange for specialty providers, as appropriate, to comment on this written material. The Department shall classify the drug(s) under consideration into one of three categories, described below, which shall trigger a predetermined procedure. The Committee shall review that determination and after review of the available material, may change the determination by a two-thirds majority vote of those members present.

Category A:

Therapeutic benefit and no projected fiscal impact or no therapeutic benefit and no projected fiscal impact.

Approval for drugs with no fiscal impact as defined herein shall be submitted to the next meeting of the Formulary Committee and shall be automatically recommended for addition to the formulary. No projected fiscal impact is defined as follows:

Reimbursement for the drug at the lowest adult daily dose for the primary indication will be compared to the average of the costs of the lowest adult daily dose for drugs within the same class, weighted by utilization for each drug within that class for the prior quarter. No consideration should be given to recommended course of therapy, improved, compliance, etc., for drugs in this category.

For combination drugs, the billed amount should be less than the combined prices of its components to have no fiscal impact.

Category B:

Therapeutic benefit and a projected fiscal impact.

80.04 PHARMACY COMMITTEES (cont.)

Therapeutic benefit is defined as a clinically (not pharmacologically) more effective drug and/or a less toxic drug than alternative therapies currently on the formulary. A drug for which the sole advantage is convenience or compliance is not considered to have a therapeutic benefit.

Therapeutic benefit will be addressed by the clinician assigned the particular drug through his or her review with a final determination made by the Committee.

Drugs with an estimated fiscal impact shall normally be added to the formulary only in one of two ways:

i. a specific appropriation of funds from the Legislature with approval of the Governor; or

ii. a deletion of other drugs from the formulary to maintain budget neutrality.

The therapeutic benefit of the drug being considered should be weighed against the therapeutic benefit of drugs already on the formulary. If the value of the drug under consideration is not thought to be great enough to justify an offsetting deletion and if
no funds are appropriated for the addition, the drug shall be put on a pending list of drugs to be added to the formulary once funds become available.

Category C:

No therapeutic benefit and a projected fiscal impact.

Drugs determined to be of no therapeutic benefit that have a projected fiscal impact shall not be added to the formulary. Such drugs would be available only through the PA process to the extent necessary for a specific individual.

b. At the conclusion of discussion of all drugs being considered at a meeting, the Committee members shall record their vote for each drug on a form to be supplied at each meeting. The Chairperson
will tally the votes and announce the Committee's preliminary determination. Written documentation of the vote will be kept on file at the OMS.

80.04 PHARMACY COMMITTEES (cont.)

c. The Department shall promulgate as a rule any additions or deletions to the formulary. After any hearing or comment period has expired, the Committee shall review any comments and take a final vote on the addition or deletion of any drugs. Any preliminary or final determination by the Committee requires a two-thirds majority vote of the members present. Inclusion of a drug on the formulary will automatically include all conventional dosage forms of that drug, with the exception of transdermal systems, sustained release and injectable dosage forms, unless specifically approved by the Formulary Committee.

d. All drugs added to the formulary will be referred to the Drug Utilization Review Committee for monitoring.

80.04-3 Academic Detailing Committee

A. Purpose

The purpose of the Academic Detailing Committee is to provide evidence based education to providers to enhance the health of residents of the State, to improve the quality of decisions regarding drug prescribing, to encourage better communication between the department and health care practitioners participating in publicly funded health programs and to reduce the health complications and unnecessary costs associated with inappropriate drug prescribing.

B. Membership
Committee

The Director of Health Care Management will appoint the Academic Detailing Committee. The Committee shall consist of at least one prescriber, pharmacist and one private insurance agency representative. Others may be asked to join based on specialty. The Committee will meet quarterly to review the status of the work group projects. The term of an appointment shall be up to four (4) years.

Work Group

The workgroup will consist of the detailers, the Department and its contractors.

C. Meetings

Meetings of the Academic Detailing Committee will be held no less than quarterly.

The work group will meet monthly. Each quarter the group will report to the Committee on the work performed, results of detailing and next steps.

80.04 PHARMACY COMMITTEES (cont.)

D. Funding

Funding for this program will be made available through the collection of fees under Maine statute, 22 M.R.S.A. §2700-A, governing clinical drug trials.

E. Outreach

The work group with the Committee's guidance, will create an outreach and prescription drugs as issued in peer reviewed, scientific, medical and academic research publications. Results and recommendations will be made available to prescribers and dispensers of drugs in the State through written information and through personal visits from staff. Program components, to the extent possible, must include information regarding clinical trials, pharmaceutical efficiency, adverse effects of drugs, evidence based treatment options and drug marketing approaches that are intended to circumvent competition from generic and therapeutically equivalent drugs. All components of the program will be reviewed and agreed upon by the Committee. The Committee shall ensure that the program adheres to standards of conduct required by 22 MRSA 2685 (3).

80.05 COVERED SERVICES

80.05-1 Drug Benefits

Reimbursement is available for the following drugs when medically necessary.

A. Legend drugs. All legend drugs found on the MaineCare program State drug file, except those drugs set forth in Section 80.05-3, which must meet the requirements of prior authorization, and those drugs set forth in Section 80.05-4, which are covered for certain diagnoses only as set forth in that Section. In addition, those legend drugs described as a non-covered service in Section 80.06 are not reimbursable.

B. Over-the-Counter drugs. Some over-the-counter drugs and supplies are covered when filled pursuant to a prescription. Over-the-counter drugs will be eligible for reimbursement, by prescription only, if such coverage is efficacious, safe, has a lower net cost, the drug has an NDC, and coverage is recommended by the Drug Utilization Review Committee and approved by the Department. A list of covered over-the-counter drugs will be posted and updated on the Department's designated website.

C. Medicare Part D Excluded Drugs

The Department will post a complete list on its designated website of Medicare Part D Excluded Drugs that are covered drugs under this Section to the extent that they are covered for MaineCare non-dual eligible members.

80.05 COVERED SERVICES (cont.)

80.05-2 Compound Prescriptions

Reimbursement may be made for a compound prescription when the Department determines that the compound prescription contains at least one ingredient that is a legend drug, present in a therapeutic quantity, and obtainable in effective strength only by prescription.

A compound prescription, which contains a laxative, stool softener, vitamin, antacid or cough and cold preparation and is prescribed solely to circumvent these MaineCare reimbursement limitations, is not covered. Reimbursement for compound drugs must not include the cost of DESI (less than effective) drugs. The primary ingredient contained in a compound prescription must be covered under a rebate agreement with the MaineCare program and have a valid NDC in the State's drug file.

80.05-3 Drugs and Products Covered for Certain Conditions/Procedures Only

Reimbursement for Methamphetamine, methylphenidate, dexmethylphenidate, and dextroamphetamine for attention deficit disorders or narcolepsy will be made only for the conditions described and only when the prescriber has written the diagnosis on the prescription.

Reimbursement for formula as a medical food product will available for a member with special nutrient needs when the prescription includes a written diagnosis.

For a member living in a nursing facility or an ICF-MR the diagnosis must be noted in the member's chart.

80.05-4 Drugs Obtained Through the Department's Mail Order Pharmacy Providers

Members are not required to obtain drugs through mail order. Members may voluntarily choose to obtain drugs through mail order. All prior authorization requirements apply to drugs obtained through mail order pharmacy providers. There is no member co-payment for drugs obtained through a mail order pharmacy provider. When refilling a prescription through a mail order pharmacy provider, refills may be provided only by a member's request; mail order pharmacy providers may not automatically refill prescriptions for members.

Providers of mail order pharmacy services must be enrolled as a Mail Order Pharmacy Provider. The Department or mail order pharmacy providers will provide members and providers with instructions for submitting a prescription by mail order.

80.06 NON-COVERED SERVICES

MaineCare does not reimburse for the following drugs or products as drugs:

A. Anorexic, or certain weight loss drugs.

80.06 NON-COVERED SERVICES (cont.)

B. Vitamins, vitamin combinations, and herbal products other than those listed on the PDL, except vitamins covered for dialysis and members with quadriplegia and paraplegia or when the criteria in Section 80.05-3 are met, and prenatal vitamins.

C. Hexachlorophene scrubs for nursing facility patients.

D. Products listed as part of the per diem rate of reimbursement in Chapter II, Section 67, Nursing Facility Services, or as defined in Section 50, ICF-MR Services, or as defined in Section 60, Medical Supplies and Durable Medical Equipment, of the MaineCare Benefits Manual or as defined in Attachment A or B of the Agreement between the Department and an assisted living facility.

E. Drugs discontinued or recalled by the manufacturers.

F. Less than Effective Drugs (DESI) as defined by the Food and Drug Administration.

G. Drugs prescribed for TB (these are normally available free of charge from the Maine HHS Public Health's Tuberculosis program). MaineCare coverage is only available after referral from the Maine HHS Public Health and MaineCare prior authorization.

H. Over-the-counter drugs except drugs listed on the Department's designated website.

I. Any drug that is for experimental use or prescribed for indications (other than those approved under OBRA 90 guidelines) or have no Food and Drug Administration (FDA) sanctioned or approved indications; unless there is evidence of two published peer-reviewed placebo-controlled randomized trials and all cost-effective choices for the specific condition have failed.

J. Drugs not covered under OBRA 90 as amended.

K. Drugs prescribed primarily for cosmetic purposes, e.g., Retin-A when used for wrinkles, Rogaine for hair growth.

L. Drugs of manufacturers not participating in the federal Medicaid Rebate program pursuant to 42 U.S.C. §1396r-8, except certain over-the-counter drugs, enteral and parenteral products and instances where no clinically equivalent drug is available.

M. Fertility drugs.

N. Drugs, Medical Food or nutritional support products prescribed for managing body weight or enhancing nutritional intake when the member is able to eat conventional foods.

O. Agents when used for the symptomatic treatment of cough and cold unless on the Preferred Drug List.

P. Early refills, as detailed in Section 80.07-7.

80.06 NON-COVERED SERVICES (cont.)

Q. Drugs used to treat sexual or erectile dysfunction are not covered, unless such drugs are used to treat conditions other than sexual or erectile dysfunction and these uses have been approved by the Food and Drug Administration.

R. Medicare Part D covered drugs for Medicare Part D eligible members.

S. Effective October 1, 2007, prescriptions in written and non-electronic form that are not executed on a tamper-resistant pad, as required by section 1903(i)(23) of the Social Security Act (42 USC §1396b(i)(23)). Providers must comply with all of the provisions of this Act in order to be appropriately reimbursed

80.07 POLICIES AND PROCEDURES

80.07-1 Regulation of Pricing

A. Drugs added and deleted and price changes with regard to drugs that fall within the parameters of the Federal Upper Limits will be updated upon notification from the United States Government Centers for Medicare and Medicaid Services (CMS).

B. Price changes with regard to drugs that fall within the MMAC guidelines and all other MaineCare drugs will be updated according to periodic review by the Department of fluctuations in the average wholesale price list maintained by the Department of Health and Human Services, OMS under the guidelines of OBRA 90, as amended. The Department is under no obligation to apply these changes retroactively.

C. Designation of an effective date for all MMAC changes will be determined together with allowance for mailing requirements in order to afford a minimum five (5) day notice to the provider.

80.07-2 Standards of Participation for Retail Pharmacy Providers

A. A pharmacy provider must be duly licensed or certified by the appropriate regulatory body in the state in which it is located, and must also be approved and accepting Medicare assignment.

B. The Department may issue a request for proposals from labelers or manufacturers and issue a contract for the provision of generic drugs.

Participant providers may be required by the Department to obtain a generic drug from labelers or manufacturers with which the Department contracts. The Department will notify providers and give instructions for compliance with this provision.

C. An out-of-state provider may participate and receive payment for dispensed drugs only if the member has been injured or suffers a disease or illness while temporarily absent from Maine. MaineCare will only reimburse drugs dispensed by out-of-state

80.07 POLICIES AND PROCEDURES (cont.)

providers on an emergency basis. Coverage of chronic or maintenance drugs is not considered an emergency. Exceptions to this requirement are 1) domestic border providers within fifteen (15) miles of the Maine/New Hampshire border, as defined in Section 80.01-31, that provide regular services to Maine members; or 2) those pharmacies that provide drugs for foster care children or other members who permanently reside in other states and are wards of the State of Maine.

D. A pharmacy provider will receive reimbursement only for drugs supplied by manufacturers who comply with the rebate requirements of the CMS in accordance with the Omnibus Budget Reconciliation Act of 1990. If a pharmacy provider does not have a drug available that is provided by a manufacturer/ labeler who complies with the rebate requirement of CMS in conformance with OBRA 90, the pharmacist must directly and individually inform the individual of other pharmacies that may carry the drug. Additionally, drugs that are otherwise covered by MaineCare but are provided from manufacturers/labelers not covered under the rebate agreement may be subject to prior authorization requirements upon thirty days written notice from the OMS. (See 80.07-4 for prior authorization policy.)

E. Any pharmacist or dispensing practitioner, whether in state or out-of-state, who wishes to submit claims for payment must be an approved MaineCare provider. Providers must submit an application (MaineCare Provider Agreement) for approval by the OMS, Provider Enrollment Unit. The OMS will review the application and notify the submitting provider whether or not he or she is accepted as a provider and if accepted, the effective date. An application may be denied, terminated or not renewed for any of the grounds set forth in the MaineCare Benefits Manual, Chapter I. A signed agreement must be on file before any reimbursement for any item or service will be made.

80.07-3 Standards for Mail Order Pharmacy Providers

Mail order pharmacy providers must be appropriately licensed by the Maine Board of Pharmacy and by the appropriate licensing authority in the state in which they are located. Mail order pharmacy providers must satisfy all MaineCare provider enrollment requirements including, but not limited to, meeting standards for quality of care and prior authorization requirements as established by the Department, accepting Medicare assignment, and operating under contract with the Department. Mail order pharmacy providers must dispense MaineCare prescription medications from within the United States.

80.07-4 Prior Authorization (PA)

A. Determining Which Drugs May Be Subject to Prior Authorization

The Department may require prior authorization for certain drugs as set forth in this Section. In all instances, MaineCare members will be assured access to all medically necessary outpatient drugs.

80.07 POLICIES AND PROCEDURES (cont.)

In determining when prior authorization will be required, the Department will consider the recommendations of the DUR Committee. The Department will provide notice of DUR meetings in newspapers, through legislative notice

procedures, to the MaineCare Advisory Committee, the Maine Medical Association, and the Maine Osteopathic Association.

Those portions of the meetings that do not involve confidential or protected information, including, to the extent possible, the process of decision making, shall be open to the public.

The determination to impose prior authorization will be based on the efficacy, safety, and net cost of any given drug and of the other drugs within the therapeutic category. The Department's determination of a drug's efficacy and safety shall be consistent with the standards set forth in (1) the peer-reviewed literature, and (2) the following compendia: the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, the DRUGDEX Information System, and American Medical Association Drug Evaluations. The Department's determination of a drug's net cost shall consider the pharmacy reimbursement amount as set forth at Section 80.09, as adjusted by any manufacturer rebates and/or supplemental rebates to be paid to the Department for that drug. The Department may not consider net cost when imposing prior authorization unless it determines that the drug to be subject to prior authorization has no significant clinical or safety advantages over one or more alternative drugs, when used for a given purpose.

The Department will provide prescribers with the list of drugs subject to prior authorization by posting and updating it on the designated website.

The Department will review previous Prior Authorization requests when reviewing a prior authorization for opioids/narcotics. Previous PA requests and medical records, as well as Lock-in or Intensive Benefits Management (IBM) records, may be considered in making decisions for current prior authorization requests.

The Department may require prior authorization of any generic drug that has a net cost that is greater than the net cost of its brand-name version.

B. Exemptions From Prior Authorization

The Department has the discretion to exempt providers and/or members from prior authorization requirements. The Department may discontinue these PA compliance exemptions any time with written notice. Exemptions are as described in this Section:

1. Provider Exemptions from Prior Authorization:

80.07 POLICIES AND PROCEDURES (cont.)

a. Three (3) Month PA Compliance Exemptions

Providers may receive a three (3) month exemption from prior authorization requirements for certain categories of drugs when they demonstrate high compliance with the Department's PDL. The Department runs quarterly reports to identify providers who prescribe ninety-five percent (95%) or more of their prescriptions, within certain categories of drugs, in compliance with the PDL. When providers are thus identified, they may receive a three (3) month exemption from PA requirements when prescribing drugs for members within the identified drug categories. The Department will notify providers in writing which drug categories are included and what dates apply to the exemption.

b. Twelve (12) Month PA Compliance Exemptions

When providers have met all requirements for the three (3) month compliance exemption described above, and have received that exemption for three (3) out of four (4) quarters of a year, the Department may grant a one (1) year exemption for prior authorization requirements when prescribing drugs for members within certain categories of drugs. The Department will notify providers in writing which drug categories are included and what dates apply to the exemption.

c. Exemptions for Specialty Providers

The Department, in consultation with the DUR Committee, and consistent with standards set forth in 80.07-4(A), may waive the prior authorization requirements for specific provider specialists on a drug-by-drug basis.

2. Member Exemptions from Prior Approval

a. Primary Insurance Exemptions from Prior Authorization

The Department may waive the prior authorization requirements for members receiving non-preferred drugs when MaineCare is the secondary payer.

80.07 POLICIES AND PROCEDURES (cont.)

b. Other Special Exemptions from Prior Authorization for Members

The Department, in consultation with the DUR Committee, and consistent with standards set forth in 80.07-4(A), may waive the prior authorization requirement for specific drugs or medical conditions, on a drug-by-drug basis for members who have been established for at least one (1) year on a drug that otherwise might be subject to prior authorization.

c. Open-Ended Member Prior Approval

The Department may grant members open-ended PAs for some specified drugs listed on the Department's designated website after having been established on a non-preferred drug and meeting all other prior authorization requirements for at least one (1) year, with the exception of any controlled substance drugs. These open-ended PAs do not need to be renewed on an annual basis. These PAs may be issued after the Department determines that the member's condition is stable, and will remain unchanged if continued on the specific drug. The Department reserves the right to review and reconsider the PA status should a new and more efficacious alternative become available.

C. Process for Seeking Prior Authorization

When the Department requires prior authorization, the member's prescriber must complete a form in writing and submit it and any required attachments, documenting the medical necessity of the prescribed drug. The Department may seek information, such as documentation of other measures that have been attempted to correct the risk/condition, the timeframe in which those other measures were attempted, and the reason for failure. The prescriber is also required to submit documentation that other drugs in the same therapeutic category are contraindicated.

The Department will notify prescribers of the drugs that are subject to prior authorization and will provide them with forms for requesting authorization setting forth the information needed to approve a request. The forms will also be available on a website designated by the Department.

The requesting prescriber must complete the form applicable to the drug for which prior authorization is sought. The prescriber must send the completed form to the Department or its designee, as instructed by the Department, by mail, fax or by hand delivery, in compliance with the Health Insurance Portability and Accountability Act (HIPAA) standards.

80.07 POLICIES AND PROCEDURES (cont.)

During regular business days, the Department or its designee will respond to a completed request for prior authorization by fax, telephone or other telecommunications device within twenty-four (24) hours of receipt.

During weekends, holidays, or any other time that the Department or its designee is not able to respond to a completed prior authorization request within twenty-four (24) hours of receipt, the pharmacy provider is authorized to provide a one-time ninety-six (96)-hour supply of any prescribed drug that is a covered drug. The Department or its designee shall respond to a completed request under this subpart on the next regular business day. The provision of a ninety-six (96)-hour supply under this subpart does not relieve the prescriber of the obligation to complete and submit the prior authorization request form.

In the event that a prescriber fails to submit a completed form for a drug requiring prior authorization, the Department or its designee may authorize the pharmacy provider to dispense a one-time four (4)-day supply of the prescribed drug. The authorization of a one-time supply under this provision does not relieve the prescriber of the obligation to complete and submit the prior authorization request form. If the prescriber has still failed to submit a completed prior authorization request by the end of the additional four (4)-day period, the Department will consider any refills of that prescription on a case-by-case basis.

Prior authorization is effective for up to twelve (12) months unless otherwise specified by the Department. In instances where coverage is continued pending an approval, the period of PA is calculated from the latter of either the end date of the previous approval or the date of the request for a hearing, unless otherwise specified by the Department.

D. Temporary Prior Authorization Requirements:

Drugs that have not been reviewed by the DUR Committee may be subject to temporary prior authorization by the Department under the following circumstances:

1. The Department may impose temporary prior authorization requirements on drugs that have been added to the State drug file since the last meeting of the DUR Committee if the Department determines that those drugs present substantial concerns regarding efficacy, safety or cost; and

2. The Department may impose temporary prior authorization requirements on drugs that are already covered by MaineCare if, since the last meeting of the DUR Committee, the Department has received new or additional information raising a substantial concern regarding efficacy, safety or cost.

80.07 POLICIES AND PROCEDURES (cont.)

Temporary prior authorization requirements imposed pursuant to this subsection shall conform to current DUR Committee prior authorization guidelines described above, and shall be effective immediately. Drugs subject to temporary prior authorization shall be reviewed at the next meeting of the DUR Committee.

80.07-5 Preferred Drug List

A. General

In order to facilitate appropriate utilization, the Department will establish a list of covered drugs, ordered by therapeutic category. This listing will be known as the Preferred Drug List or PDL. Within each therapeutic category, the Department may designate some or all drugs as preferred on the basis of efficacy, safety, and net cost. The Department's determination of a drug's efficacy and safety shall be consistent with the standards set forth in (1) the peer-reviewed literature, and (2) the following compendia: the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the DRUGDEX Information System. The Department's determination of a drug's net cost shall consider the pharmacy reimbursement amount as set forth at Section 80.09, as adjusted by any manufacturer rebates and/or supplemental rebates to be paid to the Department for that drug. The Department may not consider net cost unless it determines that the drug has no significant clinical or safety advantages over one or more alternative drugs, when used for a given purpose.

In addition to the preferred/non-preferred designation, the PDL may include information such as generic name, strength/unit, National Drug Code identification number, and brand name.

All covered drugs, whether preferred or non-preferred, are available to any eligible member for whom those drugs are medically necessary. Some drugs must have their medical necessity confirmed for a given member through the prior authorization process before the Department will provide reimbursement. When medically necessary covered brand-name drugs have an FDA approved A-rated generic equivalent available, the most cost-effective medically necessary version will be approved and reimbursed by MaineCare, since the brand-name and A-rated generic drugs have been determined by the FDA to be chemically and therapeutically equivalent. If an A-rated generic version fails due either to reported inefficacy or side effects, the member should proceed to a chemically different therapy. The Department does not make determinations as to a generic drug's equivalence or clinical efficacy compared to the brand-name version, since this is the role of the FDA.

80.07 POLICIES AND PROCEDURES (cont.)

B. Step Order

In addition to the preferred/non-preferred designations, the Department may assign some drugs on the PDL a further designation of preference within a therapeutic category. This further designation will be known as step order.

The step order is a means of reducing the need to obtain prior authorization. When a member has been prescribed all drugs at a higher step(s) within a therapeutic category, the drug at the next lower step will automatically be reimbursed for that member without requiring prior authorization. Only drugs prescribed to the member since enrollment and reflected in the Department's automated pharmacy management information Point of Purchase System will be considered in applying the step order.

Once the Department has determined that a member has undertaken a satisfactory trial of a preferred or lower-step drug, the member will not be required to repeat that drug trial in the future unless there is evidence of a change in the member's condition or new or newly acquired research that would warrant a new trial, or newly acquired evidence suggesting that the previous drug trial was inadequate.

The minimum trial periods for each preferred and step-order drug is two weeks unless otherwise stated on the Department's Preferred Drug List, or unless an acceptable clinical explanation is submitted by the attending physician. Trials with less than a two-week duration will be reviewed on a case-by-case basis. A trial will not be considered valid if non-preferred products were readily available (paid by override, individual purchase, cash, or samples, etc.), and certain drug trials may require evidence that the preferred drugs were actually tried (e.g., to confirm trials of preferred narcotics with urine drug screens).

Furthermore, adequate trials require documentation of attempts to titrate dose(s) of preferred agents toward the desired clinical response.

C. Mandatory Generic Substitution

The Department shall require substitution for a brand-name drug of a generic and therapeutically equivalent drug as required by Maine Revised Statues, Title 32, Section 13781, absent Prior Authorization from the Department. Prior Authorization requires that the prescriber has indicated that the brand-name drug must be dispensed and that the brand name drug is medically necessary.

The following shall be exempt from the requirements stated above:

1. Brand-name drugs for children under the age of eighteen (18);
2. Brand-name drugs for pregnant women;
3. Brand-name drugs required by federal law;

80.07 POLICIES AND PROCEDURES (cont.)

4. Brand-name drugs for the treatment of cancer;
5. Brand-name drugs for the treatment of HIV or AIDS;
6. Brand-name antipsychotic drugs; and,
7. Brand-name drugs that have been determined by the Department to be more cost-effective to the Department than a generic and therapeutically equivalent drug.

D. Other Limitations

1. Drug Benefit Management

The Department may provide drug benefit management to certain high-cost and/or high utilizing members of the MaineCare pharmacy benefit. The Department may identify these members by reviewing any or all of the following factors: drug costs within the top ten percent (10%) of the aggregate prescription drugs costs, utilization within the top ten percent (10%) of specific drug categories, or high costs or utilization within specific drug categories where more cost-effective drug therapies could be utilized while maintaining or improving health outcomes.

The Department may provide drug benefit management intervention for these members and/or prescribers by providing education and case management.

2. Intensive Benefits Management

The Department may provide intensive benefits management for members for whom drug benefit management does not result in the implementation of targeted recommendations. As part of the ongoing drug utilization review process, members whose drug profiles are of sufficient complexity, or who receive prescriptions from multiple prescribers, or whose prescribers have demonstrated frequent disregard for Departmental policies, may be identified for participation in intensive benefits management. Intensive benefits management may require long-term case management for members, enhanced coordination of care among providers, address inappropriate prescribing behavior, and promote cost-effective pharmaceutical care.

Intervention also may require prescriber and/or pharmacy lock-in, prior authorization of all drugs, assignment of prescribers to peer review, and enrollment of members in disease management services or intensive medical management. The Department also may require member participation in the Restriction and Narcotic Prescriber Plans, as described in Chapter IV, Section 1 of the MaineCare Benefits Manual.

80.07 POLICIES AND PROCEDURES (cont.)

Eff. 1/1/13

3. Opioid Drugs for the Treatment of Pain

a. Treatment of acute pain

Face-to-Face Visit

A face-to-face visit between the member and the prescriber must occur within four (4) days before or after the date of the prescription of an opioid drug for the treatment of acute pain.

Prior authorization is required after one (1) fifteen (15)-day prescription for opioid drugs prescribed for the treatment of pain within a twelve (12)–month period. Three (3) subsequent fourteen (14) day prescriptions are allowed within a twelve (12)-–month period~~;~~; each individual fourteen (14)- day prescription requires prior authorization. Opioid drugs prescribed in conjunction with post surgical care are exempt from the requirements stated above.

In order to maintain continuity of care for transition to longer-–term treatment, a pain management care plan consisting of a therapeutic treatment option~~,~~ must be developed and prior authorized before exhausting the third (3rd) prior authorization refill.

i. Post Surgical Care:

If the prescriber determines that the use of opioid drugs beyond the first fifteen (15)-–day~~s~~ prescription is medically necessary, further reimbursement may be available through prior authorization. A face-to-face visit between the member and the prescriber must occur within four (4) days before or after the date of the prescription requiring prior authorization.

Reimbursement is limited to a one-time prior authorization for prescriptions up to a total sixty (60)-day quantity, regardless of the number of prescriptions, outside the context of treatment for non-acute pain or exceptions described below.

ii. Long-acting, extended-release Opioids:

Eff. 1/1/13

80.07 POLICIES AND PROCEDURES (cont.)

Prior authorization on a showing of medical necessity is required for long-acting, extended-release Opioid drugs prescribed for acute pain.

b. Treatment of (long-term) non-acute pain

Reimbursement for opioid drugs beyond the limit for acute pain and post-surgical care is allowed by prior authorization if the MaineCare member participates in one (1) or more therapeutic treatment options.

In order to qualify for reimbursement for opioid drugs of long-term, non-acute pain, the prescribing physician must demonstrate that the member has:

i. Participated in a pain management care plan (when clinically appropriate); and

ii. Failed to have an adequate response to the prescribed pain management care plan; or

iii. Completed the prescribed therapeutic treatment option in accord with the member's plan and show signs of regression; or

iv. Completed at least fifty percent (50%) of the prescribed visits specified in the prescribed pain management care plan, after which the prescriber recommends that adequate control of pain will not be obtained under the therapeutic treatment.

Approved prior authorizations will not exceed twelve (12) months. After the twelve (12)-month period expires~~,~~ opioid drugs for the treatment of pain will be reimbursed only within the restrictions as listed in the acute pain section (80.07-5(D)(3)(a)), unless the provider demonstrates that the member qualifies for an exception, listed in section 80.07-5(D)(3)(iii). After the limits in the acute pain section above have been reached, the member will be subject to the requirements listed in the non-acute pain section.

c. Other terms and conditions

Eff. 1/1/13

POLICIES AND PROCEDURES (cont.)

i. Therapeutic Treatment Options:

The Department may grant prior authorization for an opioid drug when participation in all appropriate therapeutic treatments is not feasible and opioid treatment is medically necessary.

ii. Second Opinion

If a prescriber has not obtained an evaluation from a prescriber outside of the practice prior authorization will not be granted for an opioid drug~~s~~ prescribed for a medical diagnosis known typically to have a poor response to opioid drugs, as referenced on the prior authorization form. All referrals must be maintained in the member's records.

iii. Exceptions

The following shall be exempt from the prior authorization requirements stated above:

a. A MaineCare member who is receiving opioid drugs for symptoms related to HIV, AIDS and cancer and other qualifying diseases and conditions, as set forth on the Department's Preferred Drug List; or

b. A MaineCare member who is receiving opioid drugs during inpatient treatment in a hospital, in a nursing facility or during hospice care; or

c. A MaineCare member who is receiving 30 thirty milligrams (30 mg) or less of morphine sulfate equivalents on a daily basis; or

d. A MaineCare member for whom MaineCare reimbursement for opioid drugs for the treatment of addiction is restricted by limits applicable to methadone and buprenorphine and naloxone combination drugs.

E. Notification

The Department will post the PDL and any changes on the Department's designated website. The Department will also provide quarterly notification of the drugs selected for placement on the PDL, and any other changes in the PDL.

80.07 POLICIES AND PROCEDURES (cont.)

80.07-6 Dispensing Practices

Compliance with the following dispensing policies is required:

A. Dispensing practices must be in accordance with the best medical, pharmaceutical and economical practice.

B. Generic drugs as rated A in the current edition of the FDA Orange Book must be dispensed, in accordance with State law, if available at a lower cost than the brand name product.

C. Single source, brand multisource or co-licensed drugs must be dispensed in quantities not to exceed a thirty-four (34)-day supply, unless dispensed by a mail order pharmacy, which allows up to a ninety (90) day supply. FDA A-rated generic drugs must be dispensed in quantities sufficient to effect optimum economy, up to ninety (90) days. Drugs that are identified by the Department as characterized by combinations of higher than average expense, side effects and discontinuation rates, maybe subject to an initial fill limitation of a maximum fifteen days supply (trial prescription). Pharmacists will not be reimbursed for split prescriptions unless necessary to meet MaineCare policy, including but not limited to dispensing a thirty-four (34)-day supply. Also see Section 80.09. Where unit of use packaging prevents the pharmacist from measuring a thirty-four (34)-day supply (e.g., ointments, eye drops, insulin and inhalers) prescriptions shall be dispensed in a size consistent with a thirty-four (34)-day supply.

D. Payment for medications dispensed in quantities in lesser or greater amounts than therapeutically reasonable may be withheld pending contact with the prescriber to determine justification for the amount

E. All prenatal vitamins must be dispensed in quantities for up to a one hundred (100)-day supply with no more than three (3) refills.

F. Upon dispensing the prescription in person, the pharmacy provider must obtain a signature verifying receipt from the member or person picking up the prescription.

G. Providers may dispense prescriptions via telepharmacy when obtaining approval from the Department. Providers must assure that member counseling is available at the remote site from the dispensing provider or the provider delivering the prescription, and that only qualified staff, as defined by the Maine State Board of Pharmacy, deliver prescriptions. The Department may terminate this approval at any time by written notice.

A pharmacy affiliated through common ownership or control with a hospital, boarding home, ICF-MR, private non-medical institution, assisted living facility and/or nursing home is allowed to dispense covered MaineCare prescription drugs to MaineCare members in that facility. Providers must report these affiliations to the OMS Provider Enrollment Unit and

80.07 POLICIES AND PROCEDURES (cont.)

the Pharmacy Director. A registered pharmacist must dispense the drugs according to dispensing regulations. Drugs are to be billed in a manner consistent with the Department's billing guidelines and drug claim processing system (see Section 80.09) without a professional dispensing fee.

Practitioners who have been authorized to dispense drugs for MaineCare members shall not receive a dispensing fee, but will be allowed to charge the co-pay amount in addition to the acquisition cost of drugs dispensed. Records of all such dispensing must be available for review and audit.

A pharmacy provider must maintain the original or electronic copy of all prescriptions for which payment from the MaineCare program is requested. The original prescription shall be either a hard copy generated by a computer, written by the prescriber, or reduced to writing when received by the pharmacist by telephone. Information required by the Maine State Board of Pharmacy shall be recorded on each prescription and must include name of member, name of drug, quantity ordered, directions, name of prescriber, date written and initials of pharmacist filling prescription. A record of each refill must be kept on the prescription or on the profile or be available on a computer.

80.07-7 Refills

Reimbursement for refills will be made only if the following conditions are met:

A. The prescription authorizes refills.

B. No more than one (1) year has passed since the date of the original issue. Reimbursement for a drug later than one (1) year from the date of original issue requires a new prescription, subject to the limitations described in subsection 80.07-6, Dispensing Practices.

C. Reimbursement will be made for refills dispensed in no less than a thirty (30)-day supply for conditions except when the prescriber specifically directs otherwise. Mail order pharmacies may only dispense up to ninety (90) -day supplies.

D. Single source, brand multisource or co-licensed drugs must be dispensed in quantities not to exceed a thirty-four (34)-day supply, except for mail order pharmacies, which may only dispense up to ninety (90) -day supplies. If a member will suffer undue hardship from the requirement that prescriptions must be refilled every thirty-four (34) days, the provider may submit a miscellaneous prior authorization form requesting authorization to dispense a ninety (90)-day supply. FDA A-rated generic drugs must be dispensed in quantities sufficient to effect optimum economy, not to exceed ninety (90) days. Pharmacy providers will not be reimbursed for split prescriptions. See Section 80.07-6(C).

80.07 POLICIES AND PROCEDURES (cont.)

E. Early refills in excess of an eighty-five percent (85%) threshold must be authorized on a case-by-case basis through the Department or its designee, or on a basis set forth by Section 80.07-11.

F. Early refills in mail order prescription in excess of a ninety percent (90%) threshold must be authorized on a case-by-case basis through the Department or its designee, or on a basis set forth by Section 80.07-11.

G. Refills shall be mailed to the member upon request, where such mailing is the policy of the pharmacy provider with respect to the general public.

H. MaineCare may not pay for early refills because the member will be out of town for an extended period of time.

I. MaineCare may not pay for early refills for lost, stolen, or destroyed medications.

J. MaineCare may not pay for early refills for controlled substances, including Oxycontin.

K. When refilling a prescription through mail order, refills may be provided only by a member’s request; mail order pharmacies may not automatically refill prescriptions for members.

80.07-8 Pharmacist's Responsibility

The Department supports generally accepted professional judgments made by pharmacists, including the right to refuse to dispense any prescription that appears to be improperly executed or unsafe, based on the pharmacist's professional judgment. The Department expects that any pharmacist who suspects that a member may be inappropriately using a drug will report the member to the Pharmacy Unit or Program Integrity Unit, OMS, 11 State House Station, Augusta, Maine 04333-0011.

80.07-9 Restriction and Narcotic Prescriber Plans

Some members may be enrolled in the Restriction and Narcotic Prescriber Plans. See Chapter IV, Section 1, of MaineCare Benefits Manual for more details.

80.07-10 Program Integrity

Program Integrity (formerly Surveillance and Utilization) review requirements are delineated in Chapter I of the MaineCare Benefits Manual.

80.07 POLICIES AND PROCEDURES (cont.)

80.07-11 Over-Rides

The Department or its designee may authorize over-rides in certain situations to allow a pharmacy to waive standard conditions or requirements for dispensing a medication. All over-rides enabling a pharmacy to dispense a four (4) day supply or less do not constitute continued benefits under MaineCare. The following is a list of situations where the Department or its designee may authorize an over-ride to dispense medications:

A. Dosage Change

The prescriber has determined that a change in the therapy is required that results in dosage change, i.e., increased dosage or continued treatment after a starter dose.

B. Co-Payment Information Not Current

The co-payment information in the automated eligibility system is not current. This over-ride may be used only when members should be exempt from co-payment, but for whom there is a co-payment indicated, as outlined in Chapter I.

C. Ninety-Six (96) Hour Over-Ride

To enable a pharmacy to dispense up to a ninety-six (96) hour supply for situations as defined in Section 80.07-4(C). One-time over-rides enabling a pharmacy to dispense a ninety-six (96)-hour supply or less do not constitute continued benefits under MaineCare, as detailed in Chapter I.

D. Special Exceptions

When none of the conditions above apply, yet medical necessity is demonstrated. Providers must call the PA help desk to request these special exceptions, and the Department or its authorized representative will determine approval on a case-by-case basis.

80.08 CO-PAYMENT

A co-payment is to be charged by the pharmacy to each MaineCare member for each prescription filled or refilled, with the exception of prescriptions filled by the Department's mail order pharmacy providers. Members shall not pay a co-payment for drugs obtained from the Department's mail order pharmacy providers. Co-payment dispute resolution procedures are described in Chapter I of the MaineCare Benefits Manual. No pharmacy may discount the co-payment for promotional purposes.

80.08 CO-PAYMENT (cont.)

80.08-1 Pharmacy Benefits Provided By Retail and Specialty Pharmacy Providers:

A. The amount of the co-payment shall be three dollars ($3.00) per prescription, not to exceed thirty dollars ($30.00) per member per month, except as otherwise described below. The co-payment is the same for Medicare Part D Excluded Drugs.

B. The pharmacy shall not deny pharmacy services to a MaineCare member on account of the member's inability to pay a co-payment. Providers must rely upon the member's representation that he or she does not have the cash available to pay the co-payment. However, the individual's inability to pay does not eliminate his or her liability for the co-payment.

C. If a member is dispensed a drug in a quantity specifically intended by the prescriber or pharmacist to last less than one month for the member's health and welfare, only one co-payment for that drug that month is required.

D. Co-payment exemptions are described in Chapter I of the MaineCare Benefits Manual.

80.08-2 Pharmacy Benefits Provided By Department-approved Mail Order Pharmacy Providers:

Members shall have no co-payment for drugs dispensed through Department-approved mail order pharmacy providers, except as otherwise described below.

80.08-3 Benefit for People Living With HIV/AIDS

Co-payment policies for members receiving the Benefit for People Living with HIV/AIDS can be found in the MaineCare Benefits Manual, Chapter X, Section 1.

80.09 REIMBURSEMENT

80.09-1 Reimbursement Rates

MaineCare reimbursement for drugs covered under this Section will only be made for drugs of any manufacturer that has entered into and complies with a rebate agreement, except as noted in Section 80.09, and specific reporting requirements as

defined by Title XIX of the Social Security Act Section 1927 described in OBRA 90 as amended.

A. Reimbursement for Retail Pharmacy Providers:

1. Generic Drugs

The reimbursement rate for covered generic drugs shall be the lowest of the following:

80.09 REIMBURSEMENT (cont.)

a. The usual and customary charge; or

b. The Average Wholesale Price minus thirteen percent (13%) plus three dollars and thirty-five cents ($3.35) dispensing fee except as otherwise noted below; or

c. The Wholesale Acquisition Cost plus four point four percent (4.4%) plus three dollars and thirty-five cents ($3.35) dispensing fee except as otherwise noted below; or

d. The Federal Upper Limit (FUL) unless the Department meets the FUL in aggregate; or

e. The Maine maximum allowable cost plus three dollars and thirty-five cents ($3.35) dispensing fee except as otherwise noted below; or

2. Brand-name Drugs

The reimbursement rate for covered brand-name drugs shall be the lowest of the following:

a. The usual and customary charge; or

b. The Average Wholesale Price minus sixteen percent (16%) plus three dollars and thirty-five cents ($3.35) dispensing fee except as otherwise noted below; or

c. The Wholesale Acquisition Cost plus zero point eight percent (0.8%) plus three dollars and thirty-five cents ($3.35) dispensing fee except as otherwise noted below.

3. Rural Dispensing Fee Adjustment

The Department will pay a supplemental dispensing fee for prescriptions provided to members residing in rural areas in an attempt to assure continuing access to prescription services for these members. The rural dispensing fee will range from 55¢ to 65¢ per prescription dispensed to rural members, and will change on a quarterly basis to reflect the prior quarter's number of prescriptions filled. The Department will distribute the rural dispensing fee adjustment retrospectively on a quarterly basis. The Department will calculate the quarterly adjustment for each pharmacy by taking that quarter's total allotment ($500,000 per quarter) and dividing the total allotment for the quarter by the number of prescriptions filled for rural members in the quarter. The Department will then group these by pharmacy and distribute in the quarter following. Pharmacies

80.09 REIMBURSEMENT (cont.)

will be notified on a quarterly basis on the Department's designated website the amount of the adjustment for the quarter.

Rural members will be defined using a standard and federally recognized definition of rural using Metropolitan Statistical Area (MSA) designations. The Department will determine MSA/Non-MSA designation based on the zip code of the member's residence.

B. Reimbursement for Specialty Pharmacy Providers:

The reimbursement rate for Specialty Pharmacy Providers shall be the lowest of the following:

1. The usual and customary charge; or

2. The Average Wholesale Price minus seventeen (17%) plus three dollars and thirty-five cents $3.35 dispensing fee except as otherwise noted below; or

3. The Wholesale Acquisition Cost (WAC) minus zero point four percent (0.4%) plus three dollars and thirty-five cents ($3.35) dispensing fee except as otherwise noted below; or

4. The Federal Upper Limit (FUL) unless the Department meets the FUL in aggregate or the Maine maximum allowable cost plus three dollars and thirty-five cents ($3.35) dispensing fee except as otherwise noted below.

C. Reimbursement for Mail Order Pharmacy Providers:

1. Generic Drugs

The reimbursement rate for covered generic drugs obtained through mail order pharmacy providers shall be the lowest of the following:

a. The usual and customary charge; or

b. The Average Wholesale Price minus sixty percent (60%) plus a two-dollar and fifty cent ($2.50) dispensing fee except as otherwise noted below; or

c. The Wholesale Acquisition Cost (WAC) minus fifty two percent (52%) plus a two-dollar and fifty cent ($2.50) dispensing fee; or

d. The Federal Upper Limit (FUL) unless the Department meets the FUL in aggregate or the Maine maximum allowable cost plus a two-dollar and fifty cent ($2.50) dispensing fee except as otherwise noted below.

80.09 REIMBURSEMENT (cont.)

2. Brand Name Drugs

The reimbursement rate for covered brand name drugs obtained through mail order pharmacy providers shall be the lowest of the following:

a. The usual and customary charge; or

b. The Average Wholesale Price minus twenty percent (20%) plus a two-dollar and fifty cent ($2.50) dispensing fee except as otherwise noted below; or

c. The Wholesale Acquisition Cost minus four percent (4%) plus a two-dollar and fifty cent ($2.50) dispensing fee except as otherwise noted below.

D. Reimbursement for 340B Drugs
Providers or entities who purchase drugs under the 340B policy, must sign a memorandum of understanding (MOU) with the state. When the state and the entity reach an agreement on the billing process, reporting process, specific covered drugs, and pricing standards this MOU must be individualized to include the term of these components.

For entities and providers that are eligible to enroll in the 340B program, see the listing on http://www.hrsa.gov/opa/introduction.htm. All providers and entities must comply with federal and HRSA 340B rules and regulations.

E. Effective October 1, 2009 the reimbursement rate for the Seasonal Flu Vaccine and/or Allowable Immunizations as allowed by 32 MRSA § 13831, shall be the Federal Upper Limit or the Maine maximum allowable cost plus five dollars ($5.00) dispensing fee except as otherwise noted.

F. The Department's reimbursement rate will be reduced by any applicable member co-payment.

G. In accordance with Chapter I, of the MaineCare Benefits Manual, it is the responsibility of the provider to seek payment from every other source. It is the responsibility of the provider to verify a member's eligibility for MaineCare prior to providing services by requesting the individual to present his or her MaineCare ID card on each occasion that a service is provided and verifying this information as described in Chapter I of the MBM.

H. If the provider is aware that a member's eligibility is due to expire within one (1) month of the date of service, reimbursement will only be made for up to a one (1) month's supply.

80.09 REIMBURSEMENT (cont.)

I. Maine Maximum Allowable Cost (MMAC). The establishment of a MMAC is subject, but not limited, to the following considerations:

1. Multiple active rebatable manufacturers;
2. Multiple covered non-drug products available through the pharmacy POS
3. Broad wholesale acquisition, average manufacturer price, actual acquisition cost and wholesaler price spans;
4. Availability of drugs to retailers, specialty stores and mail order providers at the selected cost;
5. High volume of MaineCare member utilization; and
6. Bioequivalence or interchangeability.

The Department will periodically notify pharmacies of updates to the list of drugs affected by FUL or MMAC pricing. This information will also be available on the OMS website.

G. Reimbursement for Drugs More Expensive Than MAC or MMAC Allowances

A prescriber who requests a drug more expensive than an equivalent MAC or MMAC limited generic drug must get prior authorization for the requested product before reimbursement will be permitted. Prescribers and providers will be notified of the drugs requiring prior authorization and this list, and any updates, will be posted on the Department's designated website.

H. Reimbursement for Compounded Drugs for Retail Pharmacy Providers

Reimbursement for compounded drugs is determined by subtracting the co-payment described in Section 80.08, from the sum of the dispensing fee and the ingredient cost. The ingredient cost is the sum of the cost of the defined ingredients contained in the compounded drug. The provider must list the NDC for each active and inactive ingredient and the corresponding quantity used for each ingredient. Ingredients that are identified as DESI (less than effective) may not be included in the reimbursement for the compounded drug. Only electronic claims will be accepted.

1. Dispensing fees for compound drugs are as follows:

a. Four dollars and thirty-five cents ($4.35) except for filling insulin syringes as provided under 1(b).
b Twelve dollars and fifty cents ($12.50) for filling insulin syringes per fourteen (14) day supply.

80.10 BILLING INSTRUCTIONS

A. Billing using paper claims must be accomplished in accordance with the Department's billing requirements, "Billing Instructions for Pharmacy Services."

B. Electronic billing must be accomplished in accordance with the Department's billing requirements as described in the Electronic Media Claims rider to the Provider Agreement.

C. Mail order pharmacy providers must comply with the Department's billing requirements and submit claims through the Department's claims system.