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An Office of the
Department of Health and Human Services
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March 24, 2009

TO: Interested Parties

FROM: Anthony Marple, Director, MaineCare Services

SUBJECT: Final Rule: Maine State Services Manual, 10-144, Chapter 104, Section 4, Maine Part D Wrap Benefits.

This letter gives notice of a final rule: Maine State Services Manual, Chapter 104, Section 4: Maine Part D Wrap Benefits. In order to comply with the federal guidelines that determine the Part D Benefit parameters, the member co-payment for generic drugs has increased from $2.25 to $2.40 per prescription. The Part D Wrap Benefit covers this co-payment for eligible beneficiaries. The new co-pay amount is reflected in the Appendix to this rule.

Rules and related rulemaking documents may be reviewed at and printed from the Office of MaineCare Services website at http://www.maine.gov/dhhs/bms/rules/provider_rules_policies.htm or, 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 1-800-423-4331.

If you have any questions regarding the policy, please contact your Provider Relations Specialist at 624-7539, option 8 or 1-800-321-5557, extension option 8 or TTY: (207)287-1828 or 1-800-423-4331.

Notice of Agency Rule-making Adoption

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

CHAPTER NUMBER AND TITLE: Maine State Services Manual, Chapter 104, Section 4, Maine Part D Wrap Benefits

ADOPTED RULE NUMBER:

CONCISE SUMMARY: The Department of Heath and Human Services gives notice of a final rule Maine State Services Manual, Chapter 104, Section 4, Maine Part D Wrap Benefits. In order to comply with the federal guidelines that determine the Part D Benefit parameters, the member co-payment for generic drugs has increased from $2.25 to $2.40 per prescription. This rule is required to comply with federal guidelines. The Part D Wrap Benefit covers this co-payment for eligible beneficiaries. The new co-pay amount is reflected in the Appendix to this rule.

This rule change is not expected to impose administrative costs on small businesses.

See http://www.maine.gov/bms/rules/provider_rules_policies.htm for rules and related rulemaking documents.

EFFECTIVE DATE: March 29, 2009

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4.01 AUTHORITY

This benefit is authorized by, and these regulations are issued under, the authority of 22 M.R.S.A. § 254-D. The Commissioner of the Department of Health and Human Services has delegated the responsibility for administration of the benefit to the Office of MaineCare Services.

4.02 DEFINITIONS

4.02-1 **Authorized Representative** refers to the Department's authority pursuant to 22 M.R.S.A. § 254-D to enroll and reenroll participants 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.

4.02-2 **Beneficiary** under Medicare Part D means a person who is eligible for benefits and enrolled in a Medicare Part D plan.

4.02-3 **Brand Name Drug** is defined as a single-source drug, a cross-licensed drug, or an innovator drug.

4.02-4 **Covered Drug** is a drug for which the Department reimburses under this benefit. See Subsection 4.05 and Appendix A of this Section.

4.02-5 **Generic Drugs** are drugs other than those defined as brand-name drugs.

4.02-6 **Mail Order Pharmacy** is a pharmacy provider that dispenses prescription medications by U.S. mail or private carrier. Mail order pharmacies 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 pharmacies 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 pharmacies must dispense prescription medications from within the United States. Mail order pharmacies must process claims through the State's electronic claims processing system to the standards required by the Department.

4.02-7 **MaineCare Benefits Manual (MBM)** is the MaineCare policy set forth in Department of Health and Human Services, 10-144, Chapter 101, MaineCare Benefits Manual.

4.02-8 **MaineCare Member** means a person who receives benefits under the MaineCare Program.

4.02-9 **Medicare Part D** means the prescription drug benefit program provided under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173.

4.02 **DEFINITIONS (cont.)**

4.02-10 **Medicare Part D Excluded Drugs** are those drugs not covered by Medicare Part D pursuant to Title XIX, Section 1927 of the Social Security Act [42 U.S.C. § 1396r-8], for which the Department will continue to reimburse if otherwise covered under this Section. The Department will post a complete list of these covered drugs on its designated website, and the list will include but not be limited to the following categories of drugs: over the counter drugs, certain weight loss drugs, agents when used for the symptomatic treatment of cough and cold, vitamins/minerals, outpatient drugs for which associated tests or monitoring must be purchased exclusively from manufacturers, barbiturates, and benzodiazepins.

4.02-11 **Medicare Savings Program Eligible** refers to a participant who is also eligible for MaineCare through the Medicare Buy-In Program, as defined in the MaineCare Eligibility Manual (MEM) and designated as QMB, SLMB, or QI.

4.02-12 **National Drug Code (NDC)** is a universal drug coding system for human drugs established by the Federal Food and Drug Administration, as set forth in 21 C.F.R § 207. The FDA assigns each drug a unique identification number specifying the labeler/vendor, product, and package.

4.02-13 **Non-Preferred Drugs** are covered drugs that are not preferred drugs.

4.02-14 **OBRA 90** is the Omnibus Budget Reconciliation Act of 1990 as amended.

4.02-15 **Over-The-Counter Drug (OTC)** is a drug that can be purchased without a prescription.

4.02-16 **Participant** is an individual who is eligible for and is receiving this benefit.

4.02-17 **Pharmacy Provider** is a corporation, association, partnership, or individual that either provides pharmacy services pursuant to a provider agreement with MaineCare or is related by ownership or control to an entity that provides MaineCare or DEL Benefit services, and is also a Medicare pharmacy provider.

4.02-18 **Preferred Drugs** are covered drugs that are clinically efficacious and which have a lower therapeutic category as determined by the Department after reviewing the recommendation of the Drug Utilization Review Committee.

4.02-19 **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 may be required, step order, and any other information as determined by the Department to be helpful to participants, pharmacists, prescribers and other interested parties. This benefit utilizes the PDL referenced in Chapter 104, Section 2, Drugs for the Elderly.

4.02 **DEFINITIONS (cont.)**

4.02-20 **Prescription Drug Plan (PDP)** is a Medicare Part D plan provider that is also an approved contractor under contract with the DHHS.

4.02.21 **Retail Pharmacy** is a pharmacy that possesses a valid outpatient pharmacy license issued by the Board of Pharmacy, accepts Medicare assignment, and which serves DEL participants.

4.02-22 **Therapeutic Category** is a grouping of drugs by comparable therapeutic effect, as determined by the Department.

4.02-23 **Usual & Customary Charge** is the amount a pharmacy charges to individuals for prescription drugs for which those individuals do not have insurance coverage.

4.02-24 **Wrap Benefits** are benefits offered through this Section that may include assistance with co-payments, deductibles, premiums and gaps in coverage. Wrap benefits vary for some members, and details of the benefit are outlined in the table in Appendix A.

4.03 **ELIGIBILITY**

An individual is eligible to receive services as set forth in this Section if he or she meets the eligibility requirements established in 10-144 C.M.R. Chapter 333, and adheres to the additional requirements outlined below. Some participants may have restrictions on the type and amount of benefits they are eligible to receive under this Section.

The Department will enter enrolled participants into its electronic database. Entry into the Department's electronic database may occur in one of three ways:

1. Auto-enrollment whereby the Department automatically enrolls the participant into an approved PDP and enters the participant into the Department's database; or

2. Self-enrollment by the participant into an approved PDP. Participants who self enroll must communicate their enrollment to the Department, at which time the Department will confirm the information and enter the participant into its database. Providers should inform participants to call the Department's toll free help line at 1-866-796-2463 to report self-enrollment; or

3. If the Centers for Medicare and Medicaid Services (CMS) enrolls Medicare Savings Program (MSP) participants into an approved PDP.

DEL and Part-D eligible MaineCare members can receive wrap benefits through any CMS approved PDP.

4.04 PARTICIPATION IN MEDICARE PART D WRAP BENEFITS

Participants must exhaust other pharmacy benefits including Medicare Part D and MaineCare before using benefits under this Section.

4.04-1 Authorized Representative

The Department may act as an authorized representative for or appoint a designee to act as an authorized representative for participants who are eligible for Medicare Part D.

As an authorized representative, the Department may:

a. deem eligible and enroll and reenroll participants in a Medicare Part D plan;

b. apply for Medicare Part D benefits and subsidies on behalf of enrollees;

c. establish rules by which enrollees may opt out of participation in Medicare Part D; and

d. at its discretion, file exceptions and appeals pertaining to Medicare Part D eligibility or benefits on behalf of enrollees.

4.04-2 Coverage of Drugs Excluded from Coverage Under Medicare Part D

For participants who are eligible for Medicare Part D, the Department may provide coverage of drugs excluded by Medicare Part D to the same extent that coverage is available to participants who are not eligible for Medicare Part D.

4.05 BENEFITS

As detailed in Chapter 104, Section 2, the DEL benefit is limited to drugs of manufacturers that have both a valid rebate agreement with the federal government pursuant to 42 U.S.C. § 1396r-8 and a DEL Rebate Agreement. The Maine Part D Wrap Benefit additionally allows coverage of drugs of manufacturers that may not have both a valid DEL and federal rebate agreement. Drugs may be subject to prior authorization and the step order as set forth in Chapter 104, Section 2. The Department may refuse coverage for a drug when the prescriber cannot demonstrate medical necessity.

4.05-1 Covered Benefits

See the chart in Appendix A for a summary of Covered Benefits under this Section.

4.05-2 Prior Authorization (PA)

The Department may require prior authorization for certain drugs in this benefit, and follows guidelines as set forth in Chapter 104, Section 2.

4.05 **BENEFITS (cont.)**

4.05-3 Preferred Drug List

In order to facilitate appropriate utilization, the Department utilizes the Preferred Drug List as detailed in Chapter 104, Section 2.

4.06 **DISPENSING PRACTICES**

Retail pharmacy providers may dispense up to a 34-day supply of brand name drugs and up to a 90-day supply of generic drugs.

Drugs must be dispensed according to guidelines detailed in Chapter 104, Section 2.

4.07 **FINANCIAL PARTICIPATION (CO-PAYMENT)**

The Department requires each participant to pay a co-payment for drugs, as set forth in the chart in Appendix A. There are no exceptions. If the participant refuses to pay the co-payment, the pharmacy will deny the service.

4.08 **ELIGIBILITY LETTER**

The Department of Health and Human Services issues an eligibility card to each eligible participant enrolled in this benefit. A participant must present the eligibility card to the participating pharmacy upon request.

4.09 **AMOUNT AND DURATION OF BENEFITS**

The Department may stop reimbursing for covered drugs if, in any fiscal year, all the funds appropriated for this benefit have been expended. The Department will provide participants and participating pharmacies with prior notice of the date upon which reimbursement will cease.

4.10 **REIMBURSEMENT**

The Department will reimburse participating pharmacies only for drugs that are covered drugs as set forth in MaineCare Benefits Manual, Chapter 101, Chapter II, Section 80, Pharmacy Services, or in Maine State Services Manual, Chapter 104, Section 2, Drugs for the Elderly Benefit. This benefit is the payor of last resort. If the participant has another prescription drug coverage plan, that plan must be billed first.

4.11 **APPEALS**

Each participant has the right to an administrative hearing to appeal any decision by the Department that adversely affects that participant’s benefit. These appeal rights are set forth in Chapter 104, Section 1.

4.12 BILLING INSTRUCTIONS

Participating pharmacies must bill in accordance with the Department's billing instructions set forth in the pharmacy's MaineCare agreement.

Appendix A- MAINE PART D WRAP BENEFITS COVERAGE CHART

	Eligibility Group	Co-Payment	Premiums	Deductible	Gap	Excluded Drugs*
	Dual Eligibles Residing in Nursing Facilities	N/A	N/A	N/A	N/A	Covered as reimbursed under MaineCare Benefits Manual, Chapter II, Section 80 Pharmacy Services
	Dual Eligibles residing in Assisted Living and Level I, II, III and IV PNMI Eligibles (as reimbursed under MaineCare Benefits Manual, Chapter III, Appendices C and F, Section 97, Private Non-Medical Institution Services), or who are co-pay exempt under Chapter 1, Section 1.09-2 of the MaineCare Benefits Manual.	100% of all co-payments	N/A	N/A	N/A	Covered as reimbursed under MaineCare Benefits Manual, Chapter II, Section 80 Pharmacy Services
	All other Dual Eligibles	50% of the cost of Brand Name drugs with a cap of $10 per prescription, and 100% of the cost of generics up to $2. 40.	N/A	N/A	N/A	Covered as reimbursed under MaineCare Benefits Manual, Chapter II, Section 80 Pharmacy Services
Eff. 3-29-09	Medicare Savings Program DEL Eligibles (QMB, SLMB, QI)	50% of the cost of Brand Name drugs with a cap of $10 per prescription, and up to $2.40 per generic.	N/A	N/A	N/A	Covered as paid under Chapter 104, Section 2, DEL Policy
	DEL members eligible for Medicare Part D	50% of the cost of Brand Name drugs with a cap of $10 per prescription, and up to $2.40 per generic.	100% of Part D Premiums	50% of the Part D deductible	Members will have co-pay of 20% plus $2.	Covered as paid under Chapter 104 DEL Policy
	*Please see the following website for a list of covered Part D excluded drugs: www.mainecarepdl.org (under "General Pharmacy Info")					