STATE PLAN FOR MEDICAL ASSISTANCE UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE OF MARYLAND

12. A. Prescribed Drugs

A. The following are not covered:

- Non-legend drugs other than; insulin, Schedule V cough preparations, family
 planning products, enteric coated aspirin used in the treatment of arthritic
 conditions and any other cost effective medications as specified by the
 Program.
- 2. Any original prescription:
 - For a controlled substance dispensed more than 30 days after the prescribing date; and
 - b) For a non-controlled substance dispensed more than 120 days after the prescribing date.
- 3. Drugs supplied to hospital inpatients.
- 4. Experimental or investigational drugs.
- 5. Oral drugs or injections for central nervous system stimulants and anorectic agents when used for weight control.
- 6. Drug products for which Federal Financial Participation is prohibited pursuant to 42 CFR 441.25.
- 7. Ovulation stimulants for oral or parenteral administration.
- 8. Any Part D drug for individuals who are eligible for Medicare Part D benefits.
- 9. Drug products marketed by a manufacturer or distributor who has not entered into a rebate agreement with the Secretary of the Department of Health and Human Services as described in Section 1903 of the Social Security Act or a manufacturer who has not signed a rebate agreement with the State of Maryland prior to April 1, 1991, except Coverage will be allowed for single source drugs and innovator multiple source drugs if:
 - a) The State has made a determination that the drug is essential to the health of the beneficiaries;
 - b) The drug has been rated as 1-A by the Food Drug Administration (FDA); and
 - c) The authorized prescriber has obtained approval for use of the drug in accordance with the States' prior authorization program as described in D of this Section (Preauthorization Requirements) of the Secretary has reviewed and approved the State's determinations.
- 10. No covered drug shall be reimbursed if:
 - a) Federal financial participation from the Centers for Medicare and Medicaid Services is not available for the drug; or
 - Prior authorization was required for the drug, but was not obtained.

B. Following are covered:

Smoking Cessation Products-The Medicaid agency will provide coverage of prescription and over-the counter (OTC) smoking/tobacco cessation covered outpatient drugs for pregnant women as recommended in "Treating Tobacco Use and Dependence -2008 Update: A Clinical Practice Guideline" published by the Public Health Service in May 2008 or any subsequent modification of such guideline.

State: Maryland

MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

12. A. Prescribed Drugs 1927(d)(2) and 1935(d)(2)

 The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit -Part D.

_ T	he fo	llowing excluded drugs are covered:	
X	(a)	Agents when used for anorexia, weight loss, weight gain (Only legend products that are not CNS stimulants are covered eg. Xenical)	
	(b)	Agents when used to promote fertility	
	(c)	Agents when used for cosmetic purposes or hair growth	
x	(d)	Agents when used for the symptomatic relief cough and colds (Only legend products are covered)	
x	(e)	Prescription vitamins and mineral products, except prenatal vitamins and fluoride	
х	(f)	Nonprescription drugs (enteric coated aspirin and OTC's on the preferred drug list are covered)	
	(g)	Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee (see specific drug categories below)	
X	(h)	Barbiturates	
X	(i)	Benzodiazepines	
(The	Medi	caid agency lists specific category of drugs below)	
No excluded drugs are covered.			

STATE PLAN	UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State Agency	Maryland
	D PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR ED OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

A. Rebates

- 1. The state is in compliance with section 1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
- The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.
- A rebate agreement between the state and a drug manufacturer for drugs provided to Medicaid recipients, submitted to CMS on July 21, 2003 and entitled "State of Maryland Department of Health and Mental Hygiene Supplemental Rebate Agreement" has been authorized by CMS.
- 4. Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.
- All drugs covered by the program, irrespective of a prior authorization requirement, will comply with provisions of the national drug rebate agreement.
- 6. The State is establishing a preferred drug list with prior authorization for drugs not included on the preferred drug list pursuant to 42 U.S.C. section 1396r-8. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations.
- 7. Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses in compliance with federal law.
- The State will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with federal law.
- CMS has authorized the State of Maryland to enter into The Optimal PDL Solution (TOPS\$®). This Supplemental Drug Rebate Agreement was submitted to CMS on December 7, 2004 and has been authorized by CMS.

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Payment for drugs, effective July 1, 2011 shall be as follows:

- A. Determination of allowable cost:
 - 1. For covered multiple source legend drugs, including Schedule V cough preparations, listed on the Program's Interchangeable Drug List, allowable cost shall be the lowest of:
 - a) The Interchangeable Drug Cost (IDC) which is the maximum amount the Program will reimburse for selected, approved interchangeable multiple source drugs determined by any of the following:
 - (i) Lowest estimated acquisition cost of the generically equivalent products available in the State;
 - (ii) Price obtained by:
 - aa. Ascertaining the lowest cost from among the approved interchangeable multiple source products from each wholesaler that the Program has current and accurate pricing information, and
 - bb. Selecting as the IDC the highest of costs ascertained in (a) above; or
 - (iii)Price from a commercial generic pricing source.

NOTE: Maximum allowable costs will be reviewed and updated:

- aa. At least once every year,
- bb. Whenever there is an emergency recall by the Food and Drug Administration, or
- cc. Temporarily, if there is an acute shortage of supply from available sources.
- The Estimated Acquisition Cost (EAC) which is the lowest price of a drug product as determined by the following criteria:
 - (i) Wholesale Acquisition cost (WAC) plus eight percent;
 - (ii) Direct price plus eight percent;
 - (iii) Average Wholesale Price (AWP) less twelve percent
- Federal Generic Upper Limit (FGUL) which is the upper limit of payment for a multiple source drug for which a specific maximum allowable cost has been established by the Center for Medicare and Medicaid Services (CMS) of the Department of Health and **Human Services:**
- 2. For all other covered legend drugs, including brand name drugs for which the prescription requires the brand name drug to be dispensed, the allowable cost shall be the EAC established by the Department
- 3. For covered over-the-counter insulin the allowable cost shall be based on the AWP of the item.
- 4. For covered over the counter enteric coated aspirin the allowable cost shall be the lowest of:
 - a) IDC;
 - b) EAC; or
 - **FGUL** c)

- B. Payment for covered services to a pharmacy
 - 1. Payment for legend drugs, Schedule V cough preparations, and enteric coated aspirin will be the lower of:
 - a) The Provider's usual and customary charges, less any applicable co-payment; or
 - b) The total of:
 - (i) The allowable cost of the item;
 - (ii) Plus the applicable professional fee;
 - (iii) Less any applicable co-payment.
 - 2. Payment for over-the-counter drugs other than enteric coated aspirin shall be the lowest of:
 - a) The provider's charge according to (B)(1)(a), above; or
 - The allowable cost plus 50 percent, less any applicable copayment; or
 - c) The allowable cost of the item plus a professional fee.
 - 3. The Department may pay providers using an approved unit dose system on the basis of a daily or monthly dispensing fee per nursing home resident. The value of these fees may not be higher than the pharmacists' usual and customary charge to the non-Medicaid patients for similar services. Payments to nursing facilities will not exceed, in the aggregate, the FGUL.
- C. The professional fee is a variable fee based on the type of prescription and is \$2.56 for brand name drugs not on the preferred drug list and \$3.51 for generic drugs and for drugs on the preferred drug list, except for prescriptions for compounded intravenous therapy and prescriptions for recipients residing in nursing homes.
 - 1. For compounded prescriptions for intravenous therapy the professional fee is the lower of
 - i. \$6.89 per day of therapy; and
 - ii. \$6.89 per unit of therapy compounded.
 - 2. For prescriptions for recipients residing in nursing facilities, the professional fee is \$3.51 for brand name drugs not on the preferred drug list and \$4.46 for generic drugs and for drugs on the preferred drug list.

- D. Payment for covered services to authorized prescribers shall be made as follows:
 - 1. The Program shall reimburse an authorized prescriber for covered drugs dispensed at the lower of:
 - a) The authorized prescriber's actual acquisition cost, less any applicable co-payment; or
 - b) The allowable cost of the item, less any applicable copayment
- E. Reimbursement to an authorized prescriber for dispensing covered drugs to Medicaid recipients will be on the same basis as reimbursement to a registered pharmacist, if:
 - 1. The authorized prescriber dispenses drugs on a regular basis in the office;
 - 2. The authorized prescriber's office is not located within a 10 mile radius of a Medicaid participating pharmacy; and
 - The Program, after a consultation with the Board of Pharmacy, has verified that the authorized prescriber is dispensing drugs in accordance with accepted pharmacy standards.
- F. Payment will be made only for drugs supplied by manufacturers that have a signed national agreement or an existing approved agreement with the State, as set forth in Attachment 3.1A.
- G. The State will not pay for:
 - 1. Prescribed drugs as described in Attachment 3.1A, Prescribed Drugs, Limitations.
 - 2. Products that are not medically necessary or life sustaining or are essentially cosmetic in nature.

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Attachment 4.19A&B Page 8

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