

DEPARTMENT OF HEALTH CARE FINANCE

NOTICE OF FINAL RULEMAKING

The Director of the Department of Health Care Finance (DHCF), pursuant to the authority set forth in An Act to enable the District of Columbia to receive federal financial assistance under Title XIX of the Social Security Act for a medical assistance program, and for other purposes, approved December 27, 1967 (81 Stat. 774; D.C. Official Code § 1-307.02 (2006 Repl. & 2011 Supp.)) and section 6(6) of the Department of Health Care Finance Establishment Act of 2007, effective February 27, 2008 (D.C. Law 17-109; D.C. Official Code § 7-771.05(6) (2008 Repl.)), hereby gives notice of the adoption of the following rules which repeal sections 921 through 925 of chapter 9 (Medicaid Program) of title 29 (Public Welfare) of the District of Columbia Municipal Regulations (DCMR) and add a new chapter 27 (Medicaid Reimbursement for Pharmacy Services) of title 29 (Public Welfare) of the District of Columbia Municipal Regulations (DCMR).

Standards governing the determination of Medicaid reimbursement for prescribed multiple source drugs and other prescribed drugs were set forth in chapter 9 of title 29 DCMR. These rules will: (1) establish a new chapter 27 governing pharmacy reimbursement to include those rules previously set forth in chapter 9; (2) add additional requirements governing provider participation and the pharmacy lock-in program; (3) amend the method for determining the cost for single source prescribed drugs; and (4) clarify that barbiturates and benzodiazepines shall be excluded from coverage under Medicaid after January 1, 2013.

The pharmacy lock-in program functions as a safeguard to prevent the abuse and fraudulent use of medications. Medicaid beneficiaries who utilize Medicaid pharmacy services at a frequency or amount that is not deemed medically necessary by drug utilization review board guidelines, shall be restricted to obtaining drugs from a designated pharmacy for a limited amount of time. The corresponding amendment to the District of Columbia State Plan for Medical Assistance (State Plan) was approved by the Council of the District of Columbia through the Fiscal Year 2010 Budget Support Act of 2009, effective March 3, 2010 (D.C. Law 18-111; 57 DCR 181). The State Plan amendment governing the pharmacy lock-in program was approved by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) on December 8, 2010.

These rules include the list of the otherwise restricted classes of drugs that the Medicaid program shall continue to cover for persons who are dually eligible for Medicaid and Medicare. All barbiturates and benzodiazepines shall be covered until January 1, 2013, at which time coverage shall be excluded under Medicaid because coverage shall be made available under Medicare - Part D pursuant to the Medicare Improvement for Patients and Providers Act (MIPPA).

These rules will also change the maximum allowable reimbursement for single source prescribed drugs from the Average Wholesale Price minus ten percent (10%) to the Wholesale Acquisition Cost (WAC), plus three percent (3%), if available. WAC pricing will afford the District more discretion in re-evaluating prescription drug reimbursement policies in the absence of an AWP pricing benchmark; and simultaneously support reforms that maintain or improve access to

essential cost-effective prescription drug medications. To ensure compliance with federal law, DHCF has amended the District of Columbia State Plan for Medical Assistance (State Plan) to reflect these changes. The Council of the District of Columbia approved the corresponding State Plan amendment through the Fiscal Year 2012 Budget Support Act of 2011, effective September 14, 2011 (D.C. Law 19-0021; 58 DCR 6226. By letter dated December 22, 2011, CMS approved the corresponding State Plan Amendment with an effective date of October 1, 2011.

A notice of emergency and proposed rulemaking was published in the *D.C. Register* on September 30, 2011, at 58 DCR 8392. No comments on the notice of proposed rulemaking were received. No substantive changes have been made. The Director adopted these final rules on March 19, 2012. These rules shall become effective on the date of publication of this notice in the *D.C. Register*.

Chapter 9, MEDICAID PROGRAM, of Title 29, PUBLIC WELFARE, of the DCMR is amended as follows:

Section 921 of title 29 of the DCMR is repealed.

Section 922 of title 29 of the DCMR is repealed.

Section 923 of title 29 of the DCMR is repealed.

Section 924 of title 29 of the DCMR is repealed.

Section 925 of title 29 of the DCMR is repealed.

A new Chapter 27, MEDICAID REIMBURSEMENT FOR PHARMACY SERVICES, of Title 29, PUBLIC WELFARE, of the DCMR is added to read as follows:

CHAPTER 27 MEDICAID REIMBURSEMENT FOR FEE FOR SERVICE PHARMACY SERVICES

2700 MEDICAID PHARMACY SERVICES GENERAL PROVISIONS

2700.1 The District of Columbia Medicaid Program shall provide reimbursement for covered outpatient drugs dispensed by a licensed provider within the scope of his or her license and practice in accordance with federal, District, and state law and rules and Section 1927 of the Social Security Act.[42 U.S.C. 1396r-8].

2700.2 These rules shall govern the determination of reimbursement costs to pharmacies, including nursing home pharmacy providers, by the D.C. Medicaid Program and

the methodology for determining prescription reimbursements for prescribed multiple source drugs and other drugs provided to eligible Medicaid recipients. These rules also set forth the requirements governing the pharmacy lock-in program and provider participation requirements.

2701 PROVIDER PARTICIPATION

2701.1 A provider of pharmacy services shall be a licensed pharmacy. To participate in the District of Columbia's Medicaid Program, the provider shall:

- (a) Fully comply with any applicable District, state and federal laws or regulations governing the provision and reimbursement of pharmacy services; and
- (b) Complete and sign the Medicaid Provider Agreement.

2701.2 As a condition of participation, the provider shall be required to comply with the following requirements:

- (a) Perform prospective drug utilization review before dispensing each prescription. This shall include screenings for, but not limited to, the following:
 - (1) Therapeutic duplication;
 - (2) Drug-disease contraindications;
 - (3) Drug interactions;
 - (4) Incorrect dosage indication, or duration;
 - (5) Drug allergies; and
 - (6) Abuse or misuse;
- (b) Provide patient counseling on all matters which, in the provider's professional judgment, shall be deemed significant, including:
 - (1) Name and/or description of the medication;
 - (2) Route, dosage form, and duration of therapy;
 - (3) Directions for use;
 - (4) Common side effects;

- (5) Potential adverse reactions, contraindications;
 - (6) Storage; and
 - (7) Refill information; and
- (c) Obtain, record, and maintain patient profiles including the following:
- (1) Name, address, phone number, age and gender;
 - (2) Individual history (i.e., diseases, allergies, drug reactions);
 - (3) Comprehensive listing of medications; and
 - (4) Relevant comments.

2702 [RESERVED]

2703 REIMBURSEMENT FOR PRESCRIPTIONS

2703.1 The District of Columbia Medicaid Program shall reimburse claims submitted by participating providers for the following prescriptions:

- (a) Legend drugs that are prescribed for their labeled use; and
- (b) Over-the-counter (OTC) medications as listed in the District Medicaid Preferred Drug List and the Pharmacy Billing Manual. The following categories of OTC medications shall be covered when prescribed by a licensed provider:
 - (1) Oral analgesics with a single active ingredient (such as, aspirin, acetaminophen, and ibuprofen);
 - (2) Ferrous salts (such as, sulfate and gluconate);
 - (3) Antacids with up to three active ingredients (such as, aluminum, magnesium, and bismuth)
 - (4) Diabetic preparations (such as, insulin and syringes);
 - (5) Pediatric, prenatal, and geriatric vitamin formulations;
 - (6) Family planning drugs and supplies; and
 - (7) Senna extract, single dose preparations when required for diagnostic radiological procedures performed under the supervision of a physician.

2704 BRAND NAME DRUGS

2704.1 A prescription drug written under its brand or trade name shall be filled with its generic equivalent when one is commercially available unless:

- (a) The prescriber has indicated that the brand name drug is medically necessary for the beneficiary by writing “medically necessary” or “brand necessary” on the face of the prescription order for the drug; or
- (b) The brand is preferred on the District’s Medicaid Preferred Drug List.

2704.2 The Department of Health Care Finance (DHCF) or its agent has the authority to verify the medical necessity of a requested brand name drug.

2705 THREE (3) DAY TEMPORARY SUPPLY

2705.1 If the prescription claim is rejected by Medicaid, due to a Prior Authorization requirement, and is otherwise valid, the provider shall provide the beneficiary with a three (3) day temporary supply, unless one (1) of the following exceptions to the three (3) day supply rule is present:

- (a) The attempt to refill is too early;
- (b) The rejection is due to an error that only the provider can correct;
- (c) There are clinical issues that must be resolved;
- (d) The prescription is for a barbiturate;
- (e) The prescription is for a benzodiazepine;
- (f) The prescription is for a maintenance narcotic medication;
- (g) The individual is not eligible for Medicaid; or
- (h) There would be a medical danger, in the provider’s judgment, if a temporary supply is dispensed.

2705.2 If the beneficiary is presenting a new prescription, the provider may use discretion to determine whether there is a potential emergency to warrant a three (3) day supply.

2705.3 Providers shall not ask beneficiaries to pay for the three (3) day supply.

2705.4 Providers shall be reimbursed for the three (3) day supply and the standard dispensing fee by the Medicaid Program.

2705.5 Beneficiaries who are denied a three (3) day supply of medicine may contact the call center operated by DHCF's pharmacy benefit manager or request a hearing by contacting the Office of Administrative Hearings (OAH) or the Office of the Health Care Ombudsman if they believe their request for medication has been wrongfully denied, reduced, or not acted upon promptly.

2706 LIMITATIONS AND REQUIREMENTS FOR CERTAIN SERVICES

2706.1 All claims submitted by participating providers shall only be reimbursed if they meet relevant quantity/day supply and refill limitations established by DHCF and are available in the on-line provider manual at www.dcpbm.com.

2706.2 Prior authorization shall be required from the DHCF designated Pharmacy Benefit Manager (PBM) for the following medications:

- (a) Any drug listed as non-preferred on the District's Medicaid Preferred Drug List;
- (b) Any drug requiring medication therapy management; and
- (c) Any drug requiring closer utilization monitoring.

2706.3 The drugs or classes of drugs listed in Section 1927(d)(2) of Title XIX of the Social Security Act (42 U.S.C. § 1396r-8(d)(2)) shall be excluded from coverage unless specifically placed, either individually or by drug class, on the Medicaid Preferred Drug List of prior authorized drugs based on U.S. Food and Drug Administration (FDA)-approved indications. The following categories of medications shall be excluded from the Medicaid outpatient pharmacy benefit:

- (a) A drug which has been issued a "less than effective" (LTE) rating by the FDA or a drug that is "identical, related or similar" to an LTE drug;
- (b) A drug that has reached the termination date established by the drug manufacturer;
- (c) A drug that the drug manufacturer has not entered into or has not complied with a rebate agreement for in accordance with Section 1927(a) of Title XIX of the Social Security Act (42 U.S.C. § 1396r-8(a)), unless DHCF reviewed and determined that it shall be in the best interest of a Medicaid beneficiary to make a payment for the non-rebated drug;
- (d) Weight loss;
- (e) Fertility;
- (f) Cosmetics;
- (g) Non-prescription cough and cold;

- (h) Non-prescription vitamin and mineral products;
- (i) Erectile dysfunction; and
- (j) Medicare Part D drugs for dual eligibles entitled to receive Medicare benefits under Medicare Part A or B.

2707 REQUIREMENTS FOR RETURNED TO STOCK PRESCRIPTIONS

2707.1 All new and refilled prescriptions that have been filled for Medicaid beneficiaries but not picked up from the pharmacy within fourteen (14) days from the date of fill shall be returned to stock by the provider. The claim shall be reversed by the pharmacy benefit manager.

2707.2 The following standards shall be followed for prescriptions returned to stock due to lapse of the time requirements set forth in § 2702.1:

- (a) All medications returned to stock shall have originated at the same pharmacy to assure chain of custody;
- (b) A registered pharmacist shall assure that the medications have been stored in accordance with manufacturers' recommendations and current United States Pharmacopeia USP standards compendia;
- (c) Medications that have been reconstituted or compounded shall not be returned to stock but appropriately disposed of according to store policy; and
- (d) A licensed pharmacist shall confirm that all controlled substance prescriptions are returned to stock to minimize opportunities for tampering and diversion.

2707.3 Failure to reverse Medicaid prescription claims when such prescriptions are returned to stock may result in fraudulent and negligent health care billing. DHCF may at any time audit pharmacies to monitor such activity and seek repayment of any overpayment to provider pharmacies.

2708 MAXIMUM ALLOWABLE COST (MAC) FOR PRESCRIBED MULTIPLE SOURCE DRUGS

2708.1 The allowable cost for multiple source drugs designated by the Centers for Medicare and Medicaid Services (CMS) and included in its Medicaid Drug Rebate Program ("CMS listings") shall be the lower of the following:

- (a) The Federal Upper Limit (FUL) for multiple source drugs other than those brand names for which a prescriber has certified in writing as "Medically Necessary" or "Brand Necessary"; or

- (b) The Maximum Allowable Cost (MAC) established pursuant to § 2708.2 and 2708.3.
- 2708.2 The MAC may be established for any drug, including generics when two (2) or more A-rated therapeutically equivalent, multiple course drugs with a significant cost exist.
- 2708.3 The MAC for a drug shall be determined by:
- (a) Using comparable drug prices obtained from multiple nationally recognized comprehensive data sources including, but not limited to, pharmacy providers, wholesalers, drug file vendors, and pharmaceutical manufacturers; and
- (b) Reviewing the average wholesale price (AWP) and the wholesale acquisition cost (WAC), when available, or any current equivalent pricing benchmark, and applying the necessary multipliers to ensure reasonable access by providers to the drug at or below the MAC rate.
- 2708.4 The CMS upper limit for a drug price shall not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular patient.
- 2708.5 The handwritten phrase “Medically Necessary” or “Brand Necessary” shall appear on the face of the prescription form. If the prescription is for a nursing facility beneficiary, the handwritten phrase “Medically Necessary” or “Brand Necessary” shall be documented on the physician’s order that is maintained as part of the beneficiaries’ medical record.
- 2708.6 Neither a dual line prescription, check off-box on the prescription form, nor check off-box on the physician’s orders and plan of care shall satisfy the certification requirement.
- 2708.7 A generic drug may also be considered for MAC pricing if there are two (2) or more therapeutically equivalent, multiple source drugs with a price difference. The MAC shall be based on drug status (including non rebatable, rebatable, obsolete, and therapeutic equivalency ratings), marketplace availability, and cost. The MAC shall be based on drug prices obtained from nationally recognized comprehensive data files maintained by a vendor under contract with the DHCF.
- 2708.8 DHCF shall supplement the CMS listing by adding drugs and their prices which meet the following requirements:
- (a) The formulation of the drug approved by the FDA has been evaluated as therapeutically equivalent in the most current edition of its publication,

Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or in successor publications); and

- (b) At least two (2) suppliers list the drug (which has been classified by the FDA as category "A" in its publication, Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or in successor publications)) based on listing of drugs which are locally available.

2708.9 A pharmacy provider may identify MAC rates by visiting the District's Pharmacy Benefits Management website at www.dcpbm.com

2709 METHODS FOR DETERMINING COST FOR SINGLE SOURCE DRUGS

2709.1 Methods for determining costs of single source drugs are:

- (a) The costs for prescribed drugs which shall not exceed the WAC, plus three percent (3%), if available;
- (b) The costs for drugs that do not have a WAC shall be priced based on the direct price benchmark plus three percent (3%) as evaluated by DHCF using a national standard database; and
- (b) The cost for the WAC which shall be the price, at the time of service, obtained from a nationally recognized comprehensive data file maintained by a vendor under contract with DHCF.

2710 CLAIMS REIMBURSEMENT REQUIREMENTS FOR RETAIL PHARMACIES

2710.1 Reimbursement by the Department shall be restricted to only those drugs supplied from manufacturers that have a signed a national agreement or an approved existing agreement, as specified in Section 1927(a) of Title XIX of the Social Security Act (42 U.S.C. § 1396r-8(a)).

2710.2 All prescriptions shall comply with District, state and federal laws and regulations for legal prescriptions.

2710.3 To be reimbursable, all prescriptions that have been written, verbally ordered, or electronically initiated by a licensed prescriber shall contain the following information on the prescription form:

- (a) Name and address of patient;
- (b) Individual Prescriber's Name and National Provider Identifier (NPI);

- (c) Name, strength and quantity of the medication;
 - (d) Directions for use;
 - (e) Number of refills, if any;
 - (f) Indication for “brand medically necessary,” when applicable; and
 - (g) Signature and date of the prescriber.
- 2710.4 To be reimbursable, prescriptions for controlled substances ordered by a licensed prescriber shall contain the prescription requirements set forth in §2710.3 and include the following additional information:
- (a) The Drug Enforcement Agency (DEA) number of the licensed prescriber;
 - (b) The District of Columbia controlled substance registration number of the licensed prescriber; and
 - (c) The X-DEA number of the licensed prescriber for buprenorphine/naloxone drug preparations.
- 2710.5 Reimbursement for pharmacy claims submitted by a community or retail pharmacy provider shall be reimbursed at the lower of the following:
- (a) The allowable cost, established pursuant to the methodology described in this chapter, as appropriate, plus a dispensing fee of four dollars and fifty cents (\$4.50) per prescription; or
 - (b) The pharmacy’s usual and customary charge to the general public.
- 2710.6 Drugs covered by Medicare for persons who are dually eligible for Medicare and Medicaid shall be billed to Medicare under the Medicare Prescription Drug Benefit- Part D. The Medicaid program shall continue to provide coverage to persons who are dually eligible for the following excluded or otherwise restricted classes of drugs to the same extent that it provides coverage to all Medicaid beneficiaries:
- (a) Select agents when used for weight gain: Megesterol;
 - (b) Select prescription vitamins and mineral products except prenatal vitamins and fluoride: Folic Acid, Vitamin B 12;
 - (c) Select non-prescription drugs: analgesics, antacids, and bowel diagnostic preparation kits;

(d) All barbiturates until January 1, 2013; and

(e) All benzodiazepines until January 1, 2013.

2711 CLAIMS REIMBURSEMENT REQUIREMENTS FOR NURSING HOME PHARMACY PROVIDERS

2711.1 Effective January 1, 2006, pharmacy claims for a nursing home pharmacy provider shall be reimbursed at the lower of the following:

(a) The allowable cost, established pursuant to the methodology described in this chapter, as appropriate, plus a dispensing fee of four dollars and fifty cents (\$4.50) per non-IV (intravenous) prescription; or seven dollars and twenty-five cents (\$7.25) per IV prescription; or seventeen dollars and twenty-five cents (\$17.25) for cassette, Total Parental Nutrition (TPN) or container-related prescriptions; or

(b) The pharmacy's usual and customary charge for non-Medicaid residents.

2711.2 The allowable cost for drugs purchased by a nursing home pharmacy provider who is also a federally approved 340-B (Public Health Service) provider for Medicaid shall not exceed the actual acquisition cost for each 340-B purchased drug. Pharmacy claims for 340-B providers shall be excluded from any manufacturer's rebate.

2711.3 An additional supply of medications may be dispensed for use by a nursing facility resident during a short-term medically approved trip away from the facility during holidays or family trips.

2711.4 Prescribed drugs for purposes of nursing home pharmacy reimbursement shall not include OTC medications, syringes for diabetic preparations, geriatric vitamin formulations, or senna extract single dose preparations except when required for diagnostic radiological procedures performed under the supervision of a physician.

2712 PHARMACY LOCK-IN PROGRAM

2712.1 DHCF, along with the District of Columbia Drug Utilization Review Board (DUR Board), shall implement a Pharmacy Lock-In Program to safeguard the appropriate use of medications when an individual enrolled in the District of Columbia Medicaid Fee-for-Service Program misuses drugs in excess of the customary dosage for the proper treatment of the given diagnosis, or misuses multiple drugs in a manner that can be medically harmful. Beneficiaries listed in §2712.11 shall be exempt from the Pharmacy Lock-In Program.

- 2712.2 DHCF shall use the drug utilization guidelines established by the DUR Board in support of the restriction. The DUR Board guidelines shall require a monthly report from the Medicaid Management Information System to determine when a beneficiary may be at risk of exceeding the customarily prescribed dosages or utilization. The report shall identify beneficiaries who meet criteria, such as:
- (a) Greater than three (3) controlled substance prescriptions per month;
 - (b) Greater than three (3) prescribers for controlled substances within the last ninety (90) days;
 - (c) Greater than ten (10) prescriptions per month; or
 - (d) Three (3) or more pharmacies used per month.
- 2712.3 At least fifteen (15) days prior to the effective date of the restriction, DHCF shall notify the Medicaid beneficiary in writing of the following:
- (a) DHCF proposes to designate him or her as a restricted Medicaid beneficiary;
 - (b) The reason for the restriction;
 - (c) The effective date and duration of the restriction;
 - (d) The beneficiary's right to a hearing if he or she disagrees with the designation and procedures for requesting a hearing.
- 2712.4 The Medicaid beneficiary shall have fifteen (15) days from the date of the notice described in §2712.3 to file a request for a hearing with the OAH.
- 2712.5 If the Medicaid beneficiary requests a hearing, no further action shall be taken on the restriction designation until OAH issues a final decision.
- 2712.6 A restriction may be required for a reasonable amount of time, not to exceed twelve (12) months, without a review by the DUR Board. Subsequent restrictions shall not be imposed until after the review has concluded.
- 2712.7 DHCF shall ensure that when a lock-in has been imposed, the beneficiary shall continue to have reasonable access to prescription services of adequate quality.
- 2712.8 When a restriction is imposed upon a beneficiary, the beneficiary may choose the pharmacy of his or her choice, based upon a list of three (3) pharmacy providers DHCF identifies.

- 2712.9 When a beneficiary fails to request a hearing with OAH or fails to select a designated pharmacy after a decision has been OAH renders upholding the restriction within the specified time period, DHCF, on behalf of that beneficiary, shall designate a pharmacy for pharmacy services and send a letter to the beneficiary indicating the designated pharmacy
- 2712.10 Restrictions shall not apply in situations where emergency services are furnished to a beneficiary.
- 2712.11 Beneficiaries in skilled nursing facilities, long term care facilities, and intermediate care facility for people with developmental disabilities/intellectual disabilities (ICF/IDD) shall not be subject to the Pharmacy Lock-In Program.
- 2712.12 If a beneficiary, who is enrolled in the Medicaid Managed Care Organization (MCO) who is also required to participate in its Pharmacy Lock-In Program, subsequently becomes enrolled in the Medicaid Fee-For-Service Program, that beneficiary shall be automatically enrolled in the Medicaid Fee-For-Service Pharmacy Lock-In Program. The lock-in shall remain in force for a period not to exceed the length of the initial lock-in period first imposed by the MCO or twelve (12) months, whichever is less.

2713 EVALUATION OF SERVICE UTILIZATION

- 2713.1 Evaluation of utilization patterns may include, but are not limited to, review by the Department staff of electronic or paper records of claims submitted for prescriptions to assure compliance with the following:
- (a) All prescription and returned prescription requirements set forth in federal, District, State laws and rules;
 - (b) Requirements governing controlled substances set forth in federal, District and State laws and rules; and
 - (c) Federal requirements pertaining to legend drugs when prescribed for their labeled use.
- 2713.2 The following utilization patterns may be considered potentially abusive, not medically necessary, dangerous to the beneficiary's health and safety, or over utilization of Medicaid services, and may result in the restriction of Medicaid reimbursement for a beneficiary to a single pharmacy:
- (a) Recommendation from a medical professional or the beneficiary's primary care physician that the beneficiary has demonstrated abusive patterns and would benefit from the lock-in program;
 - (b) Use of multiple pharmacies;

- (c) Use of multiple controlled substances;
- (d) Overlapping prescription drugs with the same therapeutic class;
- (e) Diagnosis of drug abuse or drug withdrawal, or both;
- (g) Drug-seeking behavior as identified by a medical professional; and
- (h) Use of drugs or other Medicaid services determined to be abusive by the District of Columbia DUR Board.

2714 DRUG UTILIZATION REVIEW BOARD (DUR Board)

- 2714.1 Pursuant to the requirements established by 42 C.F.R. part 456, subpart K, the District of Columbia has established the Drug Utilization Review Board (DUR Board).
- 2714.2 The DUR Board shall ensure that prescribed drugs are clinically appropriate, medically necessary, cost effective, and not fraudulently obtained or prescribed.
- 2714.3 The DUR Board shall evaluate and develop guidelines for beneficiary inclusion to the fee-for service pharmacy lock-in program.

2799 DEFINITIONS

- 2799.1 For the purposes of this Chapter, the following terms and phrases shall have the meanings ascribed:

Brand - any registered trade name commonly used to identify a drug.

Compound medication - any prescription drug, excluding cough preparations, in which two (2) or more ingredients are extemporaneously mixed by a registered pharmacist.

Container - a light resistant receptacle designed to hold a specific dosage form which is or maybe in direct contact with the item and does not interact physically or chemically with the item or adversely affect the strength, quality or purity of the item.

Department of Health Care Finance (DHCF)- the executive department responsible for administering the Medicaid program within the District of Columbia effective October 1, 2008.

Generic drug- a drug that is produced and distributed without patent protection.

Legend drug- a drug that can only be dispensed to the public with a prescription.

Medicaid Drug Rebate Program- This program was created pursuant to the Omnibus Budget Reconciliation Act of 1990 (OBRA'90). The Drug Rebate program requires a drug manufacturer to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) for states to receive Federal funding for outpatient drugs dispensed to Medicaid patients.

Maintenance narcotic medication- A narcotic medication that has been dispensed in quantities sufficient for thirty (30) days or more for pain management therapy.

Multiple source drug - a drug marketed or sold by two (2) or more manufacturers or labelers.

Pharmacy benefit manager - a company under contract with managed care organizations, self-insured companies and government programs to manage pharmacy networks, provide drug utilization reviews, outcome management and disease management.

Prescribed drugs- legend drugs approved as safe and effective by the U.S. Food and Drug Administration and those over-the-counter medications which fall into the following categories:

- (a) Oral analgesics with a single active ingredient (such as, aspirin, acetaminophen, and ibuprofen);
- (b) Ferrous salts (such as, sulfate and gluconate);
- (c) Antacids with up to three active ingredients, (such as, aluminum, magnesium, and bismuth);
- (d) Diabetic preparations (such as, insulin and syringes);
- (e) Pediatric, prenatal, and geriatric vitamin formulations;
- (f) Family planning drugs and supplies; and
- (g) Senna extract, single dose preparations when required for diagnostic radiological procedures performed under the supervision of a physician.