DEPARTMENT OF HEALTH CARE FINANCE

NOTICE OF SECOND EMERGENCY AND PROPOSED RULEMAKING

The Director of the Department of Health Care Finance ("DHCF" or "Department"), pursuant to the authority set forth in An Act to enable the District of Columbia ("District") 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 (2016 Repl.)), 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) (2012 Repl.)), hereby gives notice of the adoption, on an emergency basis, of amendments to Chapter 27 (Medicaid Reimbursement for Fee for Service Pharmacies) of Title 29 (Public Welfare) of the District of Columbia Municipal Regulations ("DCMR").

These second emergency and proposed rules amend the Medicaid reimbursement methodology of covered outpatient drugs for fee for service pharmacies. The U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS") promulgated federal rules that require all states to comply with reimbursement requirements for covered outpatient drugs in accordance with 42 CFR 447.500 – 447.522.

Under the federal rules, states must use actual acquisition costs ("AAC") as part of the methodology to reimburse ingredient costs of brand name and multiple source drugs that do not have established federal upper limits ("FULs"). The federal rules also provided a definition of professional dispensing fees, which in effect requires states to restructure their professional dispensing fees to take into account additional costs (e.g., overhead, a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, and packaging). These emergency and proposed rules amend §§ 2708 through 2711 to comply with the federal requirements for reimbursement methodology and dispensing fees.

First, the federal rules require that the District change its reimbursement methodology to use actual acquisition costs ("AAC") for brand name and multiple source drugs. With this change, reimbursement for brand name drugs will be the lesser of the National Average Drug Acquisition Cost ("NADAC"), the Wholesale Acquisition Cost ("WAC"), or the usual and customary charges to the general public. Reimbursement for multiple source drugs would be the lesser of the established FUL, NADAC, WAC, the District Maximum Allowable Cost ("DMAC"), or usual and customary charges to the general public. DHCF expects a decrease in aggregate expenditures of approximately $2,681,140 in FY 2017 and a decrease in aggregate expenditures of approximately $6,434,735, each year, in FY 2018 through FY 2021.

The federal rules also require that the District reimburse pharmacies a professional dispensing fee that takes into account required factors and ensures the District rate is comparable to other jurisdictions. Taking these factors into account, the District’s reimbursement of the professional dispensing fee will increase from four dollars and fifty cents ($4.50) to eleven dollars and fifteen cents ($11.15), the fee amount derived from an analysis of a national cost of dispensing survey.
and Virginia’s state-wide professional dispensing survey. The District is also amending § 2702 to define the professional dispensing fee and clarify the types of costs included in its calculation.

The federal rules also specify the reimbursement methodologies that apply to: retail pharmacies; specialty drugs primarily dispensed through the mail; non-retail community pharmacies (e.g., institutional or long-term care pharmacy when not included as part of an inpatient stay); clotting factor from Specialty Pharmacies Hemophilia Treatment Centers, Centers of Excellence; drugs acquired via the Federal Supply Schedule (“FSS”); drugs acquired at nominal price outside of 340B Drug Pricing Program and FSS; federally approved 340B covered entity pharmacies; and 340B contract pharmacies. These proposed rules make changes to conform to these federal requirements.

An initial Notice of Emergency and Proposed Rulemaking was published in the D.C. Register on May 5, 2017, at 64 DCR 004262. Three (3) sets of comments were received. Unity Health Care (“UHC”), RELX Group, and Mary’s Center all responded to request for public comment. DHCF carefully considered all comments received and substantive changes were made as appropriate, as detailed below.

**Drug File Vendors**

RELX Group and UHC offered comments suggesting that DHCF change the manner in which it references drug file vendors in §§ 2708.2, 2708.5, and 2709.2. RELX Group and UHC both offered that the reference to the specific drug file vendor, First Data Bank, should be replaced by a more inclusive, broader reference to drug databases and drug file price compendia vendors generally. UHC offered that the reference to drug file vendors would be more accurate if replaced by a reference to “drug file pricing compendia vendors.” DHCF agrees with these suggestions and is proposing amendments §§ 2708.2, 2708.5, and 2709.2 to reflect the requested changes.

**340B Pharmacy Reimbursement**

Mary’s Center offered comments about reimbursement of entities participating under the 340B Drug Pricing Program. Mary’s Center suggested that reimbursement based on 340B AAC is inadequate and adversely impacts the ability of safety net providers to provide treatment for their patients. Mary’s Center suggested that the DHCF reimburse 340B entities using the lesser of the NADAC, the WAC, or the Pharmacy Usual and Customary (“U&C”) for both brand name and multi-source drugs.

CMS has been prescriptive concerning Medicaid reimbursement rates for 340B-covered entities. In accordance with 42 CFR 447.518(a)(2), the District’s payment methodology for drugs dispensed by 340B covered entities must be in accordance with the definition of AAC in 42 CFR 447.502 of the federal rules. For drugs purchased through the 340B program, reimbursement should not exceed the 340B ceiling price. If the drug is purchased outside the 340B program, the reimbursement should not exceed the provider’s actual acquisition costs. The rule, as drafted, complies with federal requirements. Given the need to comply with federal requirements, DHCF is not proposing amendments at this time.
Professional Dispensing Fee

UHC suggested that an enhanced professional dispensing fee should be developed for 340B-covered entities and contract pharmacies that reflects the increased compliance costs and management costs of dispensing 340B drugs. Further, UHC argued that the use of national surveys of dispensing costs and a survey of Virginia rates to establish the DHCF’s professional dispensing fee is inadequate because it does not take into account that the District is one of the highest-cost metropolitan areas in the nation.

DHCF’s analysis of national dispensing fee data and the survey of neighboring states was compliant with CMS guidance to states on the establishment of the professional dispensing fee. DHCF is not proposing additional changes at this time.

Revisions to Conform with CMS Requirements and State Plan Submission

DHCF is also proposing changes in this rulemaking to comport with changes made to the District State Plan for Medical Assistance (“State Plan”) based on comments and suggested changes by CMS. Pursuant to these comments, DHCF is proposing the following changes: (1) amendments to § 2703.1 to clarify the scope of the District’s covered prescription drug benefit and align formatting with State Plan submission; (2) amendments to § 2706.3 to clarify that agents when used for sexual or erectile dysfunction are excluded from coverage except for limited medical uses; (3) amendments to § 2706.3 to clarify that agents when used for cosmetic purposes or hair growth are excluded from coverage except when medically necessary; (4) amendments to §§ 2708.2 and 2709.1 to conform ordering with the State Plan submission; (5) amendments to § 2710.2 to clarify that the District will provide coverage for outpatient drugs consistent with the requirements of Section 1927 of the Social Security Act; (6) amendments to § 2710.7 to remove a reference to an approximation of the 340B ceiling price; (7) amendments to § 2710.9 to further clarify that drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered; and (8) clarification in § 2710.11 that otherwise excluded or restricted drugs are covered for full benefit dual eligibles to the same extent they are covered for all other Medicaid beneficiaries.

DHCF is also proposing additional changes to clarify intent: 1) amendments to § 2703.1(a) to clarify that legend drugs are covered when approved for safety and effectiveness as a prescription drug by the U.S. Food and Drug Administration (“FDA”) and prescribed for its FDA-approved indication; 2) updating the website link in §§ 2708.2(b) and 2709.2(a); 3) minor additions to § 2708.5 to clarify that the District Maximum Allowable Cost determination applies to multiple source drugs; 4) amendments to § 2710.5(c) to replace the reference to “institutional pharmacies” with “pharmacies in inpatient or residential care settings.”

Finally, DHCF is proposing edits to § 2701.2, to require, as condition of participation with the District Medicaid Program, that pharmacy service providers cooperate with District Medicaid initiatives to provide information to beneficiaries at the point of sale. District Medicaid initiatives to provide information to beneficiaries at the point of sale may include, but are not limited to: (1) prominently displaying posters or notices; and (2) providing beneficiaries with individualized
notices, letters, or pamphlets. Implementation of the changes proposed in § 2701.2(d) is not dependent upon CMS approval.

These rules correspond to a SPA, which has been approved by the Council of the District of Columbia ("Council") and CMS. The Council approved the corresponding SPA through the Fiscal Year 2017 Budget Support Act of 2016, effective October 8, 2016 (D.C. Law No. 21-160; 63 DCR 12932). CMS approved the SPA on June 28, 2017 with an effective date of May 6, 2017.

These emergency rules were adopted on March 14, 2018 and became effective immediately. These emergency rules shall remain in effect for not longer than one hundred and twenty (120) days from the adoption date or until July 12, 2018, unless superseded by publication of a Notice of Final Rulemaking in the D.C. Register.

The Director gives notice of the intent to take final rulemaking action to adopt these rules not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

Chapter 27, MEDICAID REIMBURSEMENT FOR FEE FOR SERVICE PHARMACIES, of Title 29 DCMR, PUBLIC WELFARE, is amended as follows:

Section 2701 [PROVIDER PARTICIPATION], is amended to read as follows:

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;

(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; and

(d) Cooperate with any District of Columbia Medicaid Program initiatives to provide information to beneficiaries at the point of sale including, but not limited to:

(1) Prominently displaying posters or notices; and

(2) Providing beneficiaries with individualized notices, letters, or pamphlets.
Section 2702 [RESERVED], is amended to read as follows:

2702  PROFESSIONAL DISPENSING FEE

2702.1 Medicaid reimbursement of covered outpatient drugs to fee for service pharmacies shall include a professional dispensing fee. A professional dispensing fee is a fee that:

(a) Is incurred at the point of sale or service;

(b) Pays for pharmacy costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(c) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to reasonable costs associated with delivery, special packaging and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy, and a pharmacist’s time spent:

(1) Checking the computer for information about an individual's coverage

(2) Performing drug utilization review and preferred drug list review activities;

(3) Measuring or mixing of the covered outpatient drug;

(4) Filling the container;

(5) Counseling a beneficiary; and

(6) Physically providing the completed prescription to the Medicaid beneficiary.

2702.2 The professional dispensing fee shall not include administrative costs incurred by the District in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Subsection 2703.1 of Section 2703, REIMBURSEMENT FOR PRESCRIPTIONS, is amended as follows:

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

(a) Legend drugs that are approved for safety and effectiveness as prescription drugs by the U.S. Food and Drug Administration (“FDA”) and prescribed for their FDA-approved indication;
(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 (e.g., aspirin, acetaminophen, and ibuprofen);
2. Ferrous salts (sulfate, gluconate);
3. Antacids (aluminum, magnesium, bismuth);
4. Diabetic preparations (e.g., Insulin);
5. Single agent Vitamin B1, Vitamin B6, Vitamin B12, Vitamin D, folic acid products, and geriatric vitamins;
6. Family planning drugs;
7. Senna extract;
8. Smoking cessation products;
9. Single ingredient antihistamine medications;
10. Single ingredient cough and cold medications; and
11. Select agents when used for anorexia, weight loss, or weight gain as indicated in the District Medicaid Preferred Drug List and the Pharmacy Billing Manual;

(c) Prenatal vitamins and fluoride preparations, as required under Section 1927 of the Social Security Act;

(d) Diabetic preparations (e.g., blood glucose monitors, blood glucose test strips, syringes), when prescribed by a licensed provider; and

(e) Other drugs or products used for mitigating disease in the event of a public health emergency.

Subsection 2706.3 of Section 2706, LIMITATIONS AND REQUIREMENTS FOR CERTAIN SERVICES, is amended to read as follows:

2706.3 The drugs or classes of drugs listed in § 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 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 § 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) Investigational drugs;

(e) Over-the-counter drugs provided by nursing home pharmacies;

(f) Weight loss;

(g) Fertility;

(h) Non-prescription cough and cold;

(i) Non-prescription vitamin and mineral products;

(j) Agents when used for the treatment of sexual or erectile dysfunction except for limited medical uses as required by federal law; and

(k) Agents when used for cosmetic purposes or hair growth except when the District has determined that use to be medically necessary.

Section 2708, MAXIMUM ALLOWABLE COST (MAC) FOR PRESCRIBED MULTIPLE SOURCE DRUGS, is deleted in its entirety and amended to read as follows:

REIMBURSEMENT FOR MULTIPLE SOURCE DRUGS

A multiple source drug is a covered outpatient drug for which there is at least one other drug product that is:

(a) Rated as therapeutically equivalent as reported in the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” which is available at http://www.accessdata.fda.gov/scripts/cder/ob/;

(b) Pharmaceutically equivalent and bioequivalent, as determined by the FDA; and
(c) Sold or marketed in the United States during the rebate period.

2708.2 Reimbursement for multiple source drugs shall include a professional dispensing fee in the amount of eleven dollars and fifteen cents ($11.15) plus the lesser of:

(a) The Federal Upper Limit ("FUL") of the drug for multiple source drugs, with the exception of the following:

(1) Multiple source drugs that do not have FULs; and

(2) Brand name drugs for which a prescriber has certified in writing as "Dispense as Written" or "Brand Necessary," subject to the requirements set forth under § 2708.3;

(b) The National Average Drug Acquisition Cost ("NADAC") when available, which shall be published online at: https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html;

(c) The Wholesale Acquisition Cost ("WAC") plus zero percent (0%), which shall be kept by drug file pricing compendia vendors or drug databases approved by and in use at the federal level;

(d) The pharmacy’s usual and customary charges to the general public; or

(e) The District Maximum Allowable Cost ("DMAC") established pursuant to §§ 2708.4 and 2708.5.

2708.3 Certification of "Dispense as Written" or "Brand Necessary," as described in § 2708.2, shall be subject to the following requirements:

(a) The handwritten phrase "Dispense as Written" or "Brand Necessary" shall appear on the face of the prescription form;

(b) If the prescription is for a nursing facility resident, a handwritten phrase "Dispense as Written" or "Brand Necessary" shall be documented in the resident’s medical record accompanied by a copy of the physician’s order and plan of care; and

(c) A dual line prescription form, a check-off box on the prescription form, and a check-off box on the physician’s orders and plan of care shall not satisfy the certification requirement.

2708.4 A DMAC may be established for any drug for which there are two (2) or more A-rated therapeutically equivalent, source drugs with a significant cost difference. The DMAC shall be determined taking into account drug price status (non-rebatable, rebatable), marketplace status (obsolete, regional availability),
equivalency rating (A-rated), and relative comparable pricing. Other factors that may be considered are clinical indications of generic substitution, utilization, and availability in the marketplace.

2708.5 The DMAC for multiple source drugs shall be determined as follows:

(a) Multiple drug pricing resources shall be utilized to determine the pricing for multiple source drugs, applying the necessary multipliers to ensure reasonable access by providers to the drug at or below the determined pricing benchmark; and

(b) The resources used to determine DMAC shall be maintained by a vendor under contract with DHCF, and include but are not limited to pharmacy providers, wholesalers, drug file pricing compendia vendors or drug databases approved by and in use at the federal level, and pharmaceutical manufacturers, or any current equivalent pricing benchmark.

2708.6 DHCF shall supplement the CMS listing for DMAC pricing described in § 2708.2(e) by adding drugs and their prices, which meet the following requirements:

(a) The formulation of the drug approved by the U.S. Food and Drug Administration (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.

Section 2709, METHODS FOR DETERMINING COST FOR SINGLE SOURCE DRUGS, is deleted in its entirety and amended to read as follows:

2709 REIMBURSEMENT FOR BRAND NAME DRUGS

2709.1 Reimbursement for brand name drugs shall include a professional dispensing fee in the amount of $11.15 and the lesser of:

(a) The pharmacies’ usual and customary charges to the general public; or

(b) The Actual Acquisition Cost (AAC), which shall be determined by DHCF in accordance with § 2709.2.
The AAC shall be determined by DHCF based upon the lesser of:

(a) The NADAC when available, which shall be published online at https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html; or

(b) The WAC plus zero percent (0%), which shall be kept by drug file pricing compendia vendors or drug databases approved by and in use at the federal level.

Section 2710, CLAIMS REIMBURSEMENT REQUIREMENTS FOR RETAIL PHARMACIES, is deleted in its entirety and amended to read as follows:

2710 CLAIMS REIMBURSEMENT REQUIREMENTS FOR PHARMACIES

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

2710.2 To be reimbursable, all prescriptions shall comply with District and federal laws and regulations for legal prescriptions. The District of Columbia will provide reimbursement for covered outpatient drugs consistent with prior authorization and other requirements under § 1927 of the Social Security Act.

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;

(c) Name, strength, and quantity of the medication;

(d) Directions for use;

(e) Number of refills, if any;

(f) Indication for “Dispense as Written” or “Brand 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 The reimbursement methods for brand name drugs and multiple source drugs, set forth under §§ 2708 and 2709 of this Chapter, shall apply to the following claims, as appropriate:

(a) Pharmacy claims for retail pharmacy providers;

(b) Specialty drugs primarily dispensed through the mail;

(c) Claims from pharmacies in inpatient or residential care settings when not included as part of an inpatient stay;

(d) Clotting factors from Specialty Pharmacies Hemophilia Treatment Centers, Centers of Excellence;

(e) Drugs acquired via the Federal Supply Schedule ("FSS"); and

(f) Drugs acquired at nominal price (outside of 340B Drug Pricing Program and FSS).

2710.6 Except for 340B of the Public Health Service Act (340B) contract pharmacies, federally approved 340B covered entity pharmacies that include Medicaid claims in the 340B Drug Pricing Program shall be reimbursed in accordance with §§ 2710.7 or 2710.8, as applicable, plus the professional dispensing fee of eleven dollars and fifteen cents ($11.15).

2710.7 The submitted ingredient cost for drugs purchased through the Federal Public Health Service’s 340B Drug Pricing Program shall mean the 340B acquisition cost, and shall be reimbursed no higher than the 340B ceiling price as published. 340B covered entity pharmacies shall include the National Council for Prescription Drug Program (NCPDP) indicator on each claim for drugs purchased through the 340B program.
2710.8 Drugs purchased outside of the 340B program shall be submitted without the NCPDP 340B claim indicator described in § 2710.7, and shall be reimbursed using the methodology described in §§ 2708 and 2709, as applicable, plus up to the established professional dispensing fee of eleven dollars and fifteen cents ($11.15). All applicable Federal and District Supplemental rebates shall be applied to claims submitted without the NCPDP 340B claim indicator.

2710.9 Drugs acquired through the 340B drug pricing program and dispensed by 340B contract pharmacies are not covered. DHCF shall not reimburse prescription claims submitted by 340B contract pharmacies.

2710.10 340B contract pharmacies shall exclude Medicaid claims from the 340B Drug Pricing Programs.

2710.11 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 provides coverage to persons who are dually eligible for excluded or otherwise restricted classes of drugs to the same extent that it provides coverage to all Medicaid beneficiaries.

2710.12 Nursing facility pharmacies shall be reimbursed for an additional supply of covered medications when dispensed for use by a beneficiary residing in a long-term care facility during a short-term medically approved trip away from the facility.

2710.13 Nursing facility pharmacies’ reimbursement for prescribed drugs for patients in their care shall not include the following prescription drugs and items which have been included in the Medicaid reimbursement rates for nursing facilities:

(a) Over-the-counter medications;

(b) Syringes for diabetic preparations;

(c) Geriatric vitamin formulations; and

(d) Senna extract single dose preparations except when required for diagnostic radiological procedures performed under the supervision of a physician.

Section 2711, CLAIMS REIMBURSEMENT REQUIREMENTS FOR NURSING HOME PHARMACY PROVIDERS, is deleted in its entirety and amended as follows:

2711 [RESERVED]
Section 2799, DEFINITIONS, is amended to read as follows:

2799 DEFINITIONS

For purposes of this chapter, the following terms and phrases shall have the meanings ascribed:

Actual Acquisition Costs – DHCF’s determination of the pharmacy providers’ actual prices paid to acquire drug products marketed or sold by specific manufacturers.

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

Brand name drugs – A single source or innovator multiple source 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 – The executive department responsible for administering the Medicaid program within the District of Columbia.

Federal Supply Schedule – A multiple award, multi-year federal contract for medical equipment, supplies, pharmaceutical, or service programs that is available for use by federal government agencies that complies with all federal contract laws and regulations. Pricing is negotiated based on how vendors do business with their commercial customers.

Federal Upper Limit – The upper limits of payment established by the Centers for Medicare and Medicaid Services, consistent with the requirements set forth under 42 CFR §§ 447.512 – 447.516.

Generic drug – A drug that is produced and distributed without patent protection.

Investigational drug – A drug that is under study but does not have permission from Food and Drug Administration to be legally marketed and sold in the U.S.

Legend drug – A drug that can only be dispensed to the public with a prescription.
Medicaid Drug Rebate Program – The program created pursuant to the Omnibus Budget Reconciliation Act of 1990, approved November 5, 1990 (104 Stat. 1388, 42 USC § 1396r-8) (OBRA 1990), which 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.

Pharmacy benefit manager – A company under contract with DHCF to manage pharmacy networks, provide drug utilization reviews, outcome management and disease management.

340B Covered Entity Pharmacy – An in-house pharmacy of an entity that meets the requirements set forth in § 340B(a)(4) of the Public Health Services Act.

340B Contract Pharmacy – A pharmacy dispensing drugs on behalf of a covered entity described at § 340B(a)(4) of the Public Health Services Act.

X-DEA number – A unique identification number (x-number) assigned by the Drug Enforcement Administration under the Drug Addiction Treatment Act of 2000 in order to prescribe or dispense buprenorphine/naloxone drug preparations.

Comments on these rules should be submitted in writing to Claudia Schlosberg, J.D, Senior Deputy Director/State Medicaid Director, Department of Health Care Finance, Government of the District of Columbia, 441 4th Street, NW, Suite 900, Washington DC 20001, via telephone on (202) 442-8742, via email at DHCFPubliccomments@dc.gov, or online at www.dcregs.dc.gov, within thirty (30) days of the date of publication of this notice in the D.C. Register. Additional copies of these rules are available from the above address.