DEPARTMENT OF HEALTH CARE FINANCE

NOTICE OF FINAL 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 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 final 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).

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 is increasing under this rulemaking from four dollars and fifty cents ($4.50) to eleven dollars and fifteen cents ($11.15).

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 final rules make changes to conform to these federal requirements. 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.

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 made substantive changes. DHCF separately determined 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 when a beneficiary's request for pharmacy benefits is denied. Implementation of the changes set forth in Subsection 2701.2(d) are not dependent upon CMS approval.

A Notice of Second Emergency and Proposed Rulemaking was published in the *D.C. Register* on March 23, 2018, at 65 DCR 003013. DHCF received no comments and made no substantive changes to the rule. DHCF made a technical correction to Subsection 2706.1 to properly identify the website address where the on-line provider manual is located.

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 10775 (August 26, 2016)). CMS approved the SPA on June 28, 2017 with an effective date of May 6, 2017.

These final rules were adopted on July 3, 2018 and shall become effective on 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 Bl, Vitamin B6, Vitamin Bl2, 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.

Subsections 2706.1 and 2706.3 of Section 2706, LIMITATIONS AND REQUIREMENTS FOR CERTAIN SERVICES, are amended to read as follows:

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.dc-pbm.com.

2706.3 The drugs or classes of drugs listed in § 1927(d)(2) of Title XIX of the Social Security Act (42 USC § 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 USC § 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:

2708 REIMBURSEMENT FOR MULTIPLE SOURCE DRUGS

2708.1 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 DETRMINING 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.

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 USC § 1396r-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

2799.1 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.