DEPARTMENT OF HEALTH CARE FINANCE

NOTICE OF 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 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 new federal rules that require all states to comply with new reimbursement requirements for covered outpatient drugs in accordance with 42 CFR §§ 447.500 – 447.522 effective April 1, 2017. 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 new 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 Subsection 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 $3,217,000 in FY 2017 and a decrease in aggregate expenditures of approximately $6,434,700, each year, in FY 2018 through FY 2021.

The federal rules also require that the District reimburse pharmacies a new 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 Section 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 emergency and proposed rules make changes to conform to these federal requirements. In addition, the emergency and proposed rules amend the limitations and requirements for certain services in order to specify that investigational drugs are not reimbursable in the District. Under the emergency and proposed amendments, the rule will no longer include a tiered dispensing fee for nursing facility pharmacies; rather, the professional dispensing fee will be the same for all pharmacies, including nursing facility pharmacies. Furthermore, the emergency and proposed rule amends the definitions in Section 2799 by: (1) adding new definitions for the terms actual acquisition costs, brand name drugs, federal supply schedule, federal upper limits, investigational drugs, and 340 entities; (2) amending the definition of pharmacy benefit manager; and (3) amending the definition for multiple source drugs and moving the definition to Subsection 2708.1.

The District is also amending Sections 2703 and 2706 in order to allow the District to expand its reimbursement for needed medications and to achieve consistency with the District State Plan for Medical Assistance ("State Plan"). Specifically, the list of reimbursable prescription drugs includes smoking cessation products, single ingredient antihistamine medications, geriatric vitamins, and other over-the-counter medications found to be medically necessary that are FDA-approved or medically indicated based on documentation in official compendia or peer-reviewed medical literature. The Patient Protection and Affordable Care Act of 2010, approved March 23, 2010 (Pub. L. No. 111-148, 124 Stat. 119) requires coverage of smoking cessation treatment. Due to the need for single ingredient antihistamine products among Medicaid-enrolled adults and children, the emergency and proposed rule provides Medicaid reimbursement for these drugs. The inclusion of the broad category of over-the-counter medications among covered drugs conforms to a previously approved State Plan Amendment ("SPA"), which includes this category as an exception to non-covered drugs. Additionally, the category of over-the-counter medications approved by the U.S. Preventive Services Task Force allows the District to have the flexibility to react to epidemics or other public health concerns and cover needed drugs that are FDA-approved. The list of drugs that are excluded from reimbursement includes over-the-counter drugs provided by nursing home pharmacies in order to achieve consistency with a previously approved SPA. These particular drugs are specified as being excluded since reimbursement for these drugs is already included in the nursing homes’ daily rates.

The District Medicaid Program is also amending the State Plan. These rules correspond to the SPA, which requires approval 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, signed August 18, 2016 (D.C. Act 21-488; 63 DCR 10775 (August 26, 2016)).

Because the federal law requires that States have these rules in place by April 1, 2017, these emergency rules shall become effective for services rendered on or after April 1, 2017, once the
corresponding SPA has been approved by CMS with an effective date of April 1, 2017, or the effective date established by CMS in its approval of the corresponding SPA, whichever is later. These emergency rules were adopted on April 27, 2017 and shall remain in effect for not longer than one hundred and twenty (120) days from the adoption date or until August 25, 2017, 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 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.
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 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 (e.g., aspirin, acetaminophen, and ibuprofen);

(2) Ferrous salts (sulfate, gluconate);

(3) Antacids (aluminum, magnesium, bismuth);

(4) Diabetic preparations (e.g., Insulin, syringes);

(5) Prenatal vitamins and Fluoride; pediatric multivitamins; single agent Vitamin Bl, Vitamin B6, Vitamin Bl2, Vitamin D, and folic acid products; and geriatric vitamins;

(6) Family planning drugs;

(7) Senna extract, single dose preparations when required for diagnostic radiological procedures performed under the supervision of a physician;

(8) Smoking cessation products;

(9) Single ingredient antihistamine medications; and

(10) Other over-the-counter, US Preventative Services Task Force recommended, medications found to be medically necessary that are FDA-approved or medically indicated based on documentation in official compendia or peer-reviewed medical literature.

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

(j) Erectile dysfunction drugs except for limited medical uses as required by federal law.

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
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 National Average Drug Acquisition Cost ("NADAC") when available, which shall be published online at: https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Pharmacy-Pricing.html;

(b) The Wholesale Acquisition Cost ("WAC") plus zero percent (0%), which shall be kept by drug file vendors such as First Data Bank;

(c) 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 Subsection 2708.3;

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

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

2708.3 Certification of "Dispense as Written" or "Brand Necessary," as described in Subsection 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 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 a drug 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 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 vendors such as First Data Bank, and pharmaceutical manufacturers, or any current equivalent pricing benchmark.

2708.6 DHCF shall supplement the CMS listing for DMAC pricing described in Subsection 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 be at the lesser of:

(a) The Actual Acquisition Cost, which shall be determined by DHCF in accordance with Subsection 2709.2, plus a professional dispensing fee in the amount of $11.15; or

(b) The pharmacies’ usual and customary charges to the general public.

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-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Pharmacy-Pricing.html; or

(b) The WAC plus zero percent (0%), which shall be kept by drug file vendors such as First Data Bank.

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 Section 1927(a) of Title XIX of the Social Security Act (42 U.S.C. § 1396r-8(a)).

2710.2 To be reimbursable, 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;

(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 Subsection 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 Sections 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) Institutional pharmacy claims 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 (Public Health Service) contract pharmacies, federally approved 340B covered entity pharmacies that include Medicaid claims in the 340B Drug Pricing Program shall be reimbursed in accordance with Subsections 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 or calculated by Average Manufacturer Price minus Unit Rebate Amount. 340B 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 Subsection 2710.7, and shall be reimbursed using the methodology described in Sections 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 State
Supplemental rebate shall be applied to claims submitted without the NCPDP 340B claim indicator.

2710.9 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 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 limited to: single agent Vitamin B1, Vitamin B6, Vitamin B12, Vitamin D, and folic acid products; and

(c) Select non-prescription drugs: analgesics with a single active ingredient, antacids, and bowel diagnostic preparation kits.

2710.12 An additional supply of covered medications may be 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:
Section 2799, DEFINITIONS, is amended to read as follows:

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.