

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) and 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)) hereby gives notice of the adoption of amendments to Section 922 of Title 29 of the District of Columbia Municipal Regulations (DCMR), entitled “Methods for Determining Costs of Prescribed Multiple Source Drugs”, and section 925.99 of Title 29 DCMR entitled “Definitions”.

These rules will establish a Maximum Allowable Cost (MAC) program for prescription drugs covered by the Medicaid program. The MAC program is a payment mechanism designed to standardize the reimbursement rates for multi-source drugs when there are at least two (2) drugs in the therapeutic category. The MAC rate will be the maximum amount the District will reimburse a pharmacy for affected multi-source drugs. Implementation of the MAC standardizes the rate of reimbursement to pharmacies, thus encouraging pharmacies to obtain the lower priced multi-source drug for dispensing purposes. Medicaid state agencies have adopted MAC programs as a best practice to contain the increasing cost of prescription drugs needed by Medicaid recipients. The MAC program will work together with the Preferred Drug List to help DHCF obtain the lowest price for prescription drugs, consistent with quality of care standards. DHCF estimates savings from the new MAC of five hundred thousand dollars (\$500,000) for fiscal year 2010.

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 resolution to request a State Plan Amendment creating a MAC program through Res. 16-786 on August 11, 2006. The U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, approved the corresponding State Plan Amendment on August 19, 2009.

A notice of proposed rulemaking was published in the *D.C. Register* on October 9, 2009 (56 DCR 8055). No comments on the proposed rules were received. No substantive changes have been made. These rules shall become effective one (1) day after publication of this notice in the *D.C. Register*.

Chapter 9 of Title 29 of the District of Columbia Municipal Regulations (Public Welfare) is amended as follows:

- 1. Section 922 (Methods for Determining Costs of Prescribed Multiple Source Drugs) is amended to read as follows:**

922 METHODS FOR DETERMINING COSTS OF PRESCRIBED MULTIPLE SOURCE DRUGS

- 922.1 The allowable cost for multiple source drugs designated by the Centers for Medicare and Medicaid Services (CMS) and included in its listing shall be the lower of the following:
- (a) The Federal Upper Limit (FUL) for multiple source drugs other than those brand name drugs for which a prescriber has certified in writing as “Medically Necessary” or “Brand Necessary”; or
 - (b) The Maximum Allowable Cost (MAC) established pursuant to §§ 922.3 and 922.4 of this chapter.
- 922.2 The Department of Health Care Finance (DHCF) shall restrict payment to only those drugs supplied from manufacturers that have signed a national agreement, or have an approved existing agreement, as specified in Section 1927(a) of Title XIX of the Social Security Act (42 USC 1396r-8(a)).
- 922.3 The MAC may be established for any drug when two (2) or more A-rated therapeutically equivalent, multiple source drugs with a significant cost difference exist.
- 922.4 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 and the wholesale acquisition cost and applying necessary multipliers to ensure reasonable access by providers to the drug at or below the MAC rate.
- 922.5 The CMS upper limit for a drug price and the MAC shall not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular patient.
- 922.6 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 in the beneficiary’s medical record accompanied by a copy of the physician's order and plan of care.
- 922.7 Neither a dual line prescription form, 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.

922.8 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 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.

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

2. Section 925.99 is amended as follows:

A. The following new definitions are added in alphabetical order within the current list of definitions:

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

DHCF – Department of Health Care Finance.

FUL – the federal upper limit established by CMS.

PBM – pharmacy benefits manager

B. The definitions of the terms "multiple source drug" and "prescribed drugs" are amended to read as follows:

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

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 (i.e., aspirin, acetaminophen, ibuprofen, etc.);
- (b) Ferrous salts (i.e., sulfate, gluconate, etc.);
- (c) Antacids with up to three active ingredients, (i.e., aluminum, magnesium, bismuth, etc.);
- (d) Diabetic preparations (i.e., insulin, syringes, etc.);
- (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.
- C. The definitions of the term “Department of Health, Medical Assistance Administration” is deleted.**