

DEPARTMENT OF HEALTH CARE FINANCE

NOTICE OF FINAL RULEMAKING

The Director of the Department of Health Care Finance (DHCF or the 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 (the 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. & 2019 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) (2018 Repl.)), hereby gives notice of the adoption of amendments to Chapter 27 (Medicaid Reimbursement for Fee for Service Pharmacy Services) of Title 29 (Public Welfare) of the District of Columbia Municipal Regulations (DCMR), by amending Section 2799 (Definitions) and adding a new Section 2715 (Pharmacists' Administration Services).

This rule will allow the District Medicaid Program to reimburse pharmacies for administration of immunizations, vaccines, and emergency anaphylaxis agents that are required to treat an anaphylactic reaction caused by an immunization or vaccine. District laws and regulations permit pharmacists to administer immunizations, vaccines, and emergency anaphylaxis agents under § 6512 of Title 17 DCMR. This rule requires pharmacists' administration services to meet seven conditions: (1) licensure and practice within the scope of practice authorized under the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code §§ 3-1201 *et seq.* (2016 Repl. & 2019 Supp.)) and Chapter 65 of Title 17 DCMR or the applicable professional practices act within the jurisdiction where services are provided; (2) certification by the D.C. Board of Pharmacy to administer immunizations and vaccines in accordance with § 6512 of Title 17 DCMR or the applicable professional practices act within the jurisdiction where services are provided; (3) the administration of immunizations, vaccines, and emergency anaphylaxis agents that are covered under the District's Medicaid State Plan for Medical Assistance ("State Plan"); (4) administration of immunizations and vaccines must be supported by and consistent with a written protocol, valid prescription, or physician standing order as required under § 6512 of Title 17 DCMR or the applicable professional practices act within the jurisdiction where services are provided; (5) administration of emergency anaphylaxis agents must be supported by and consistent with a written protocol, consistent with the requirements of § 6512 of Title 17 DCMR or the applicable professional practices act within the jurisdiction where services are provided, and must be required to treat an emergency anaphylactic reaction that is caused by the administration of an immunization or vaccine; (6) the pharmacy in which the pharmacist is located shall be a Medicaid-enrolled provider in compliance with provider screening and enrollment requirements set forth under Chapter 94 of Title 29 DCMR; (7) the pharmacist must notify the beneficiary's primary care physician if a flu vaccine or a vaccine that is not covered under the Vaccine for Children (VFC) Program is administered to a child under nineteen (19). This rule also sets forth that pharmacies may be reimbursed administration fees, and outlines separate rates for injectable products and intranasal products. In addition, the rule allows the District to update the administration fees, subject to the requirements governing the Medicaid Fee Schedule as set forth under § 988 of Title 29 DCMR.

This rulemaking amends Chapter 27 of Title 29 DCMR by incorporating the Medicaid reimbursable services that pharmacists may deliver in the District. Finally, these rules would also further amend Chapter 27 (Medicaid Reimbursement for Fee for Service Pharmacy Services) by adding new definitions to § 2799 for the following terms: administer, administration fee, anaphylaxis, emergency anaphylaxis agent, immunization, vaccination, and written protocol.

These rules correspond to an amendment to the District's State Plan for Medical Assistance (State Plan), which was approved by the U.S. Department of Health and Human Services, Centers for Medicaid and Medicare Services (CMS) on February 25, 2020. These rules became effective for services rendered on or after February 15, 2020. The District Medicaid Program estimates that the rule will have little to no impact on District or federal expenditures.

A Notice of Emergency and Proposed Rulemaking was published on February 14, 2020 in the *D.C. Register* at 67 DCR 1633. The following comment was received from the National Association of Chain Drug Stores (NACDS). The comment supports expanded access to vaccines through pharmacies by allowing them to bill for vaccine administration, which this regulation does. Accordingly, we have not changed the rule in response to the supportive comment below.

NACD applauds DHCF for identifying opportunities to expand access to affordable and quality care by allowing licensed pharmacists to bill for vaccine administration. NACD comments that the prevalence of vaccine-preventable diseases in adults remains a significant public health issue in the U.S. NACD provides data that shows low immunization uptake and immunization rates in the U.S. and the District. NACD further states that given the status of population health and the physician shortage, there is great need for Washington, DC residents to have additional healthcare destinations to receive high quality, affordable, and convenient care. NACD further explains that community pharmacists are highly qualified and well-positioned in local communities to manage and provide quality preventive care, and are oftentimes the most readily accessible healthcare provider, which should help improve health outcomes, address gaps in health care coverage, and save downstream healthcare costs.

The Director adopted these rules as final on May 28, 2020 and they shall become effective on the date of publication of this notice in the *D.C. Register*.

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

A new Section 2715 is added to read as follows:

2715 PHARMACISTS' ADMINISTRATION SERVICES

2715.1 Medicaid reimbursement for pharmacists' administration services, provided consistent with the requirements set forth in 42 CFR § 440.60(a) and the provisions set forth in this section, shall be limited to:

- (a) Administering Medicaid-covered immunizations, vaccines, and emergency anaphylaxis agents to adults; or

- (b) Administering Medicaid-covered immunizations, vaccines and emergency anaphylaxis agents that are not covered under the Vaccines For Children (“VFC”) Program.

2715.2 The Department of Health Care Finance (“DHCF”) shall reimburse a pharmacy when a pharmacist administers to a Medicaid beneficiary any of the following covered drugs:

- (a) Immunizations;
- (b) Vaccines; and
- (c) Emergency anaphylaxis agents required to treat an emergency anaphylactic reaction that is caused by an immunization or vaccine.

2715.3 In order to be eligible for Medicaid reimbursement, pharmacists who provide the services described in § 2715.2 must meet the following requirements:

- (a) Be licensed and practicing within the scope of practice authorized under the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code §§ 3-1201 *et seq.* (2016 Repl. & 2019 Supp.)) and Chapter 65 of Title 17 of the District of Columbia Municipal Regulations (“DCMR”) or the applicable professional practices act within the jurisdiction where services are provided;
- (b) Be certified by the D.C. Board of Pharmacy to administer immunizations and vaccines in accordance with § 6512 of Title 17 DCMR or the applicable professional practices act within the jurisdiction where services are provided;
- (c) Administer immunizations and vaccines that are covered under the District’s Medicaid State Plan for Medical Assistance (“State Plan”);
- (d) Administer emergency anaphylaxis agents that are:
 - (1) Specified in a written protocol, as required under § 6512 of Title 17 DCMR or the applicable professional practices act within the jurisdiction where services are provided, and covered under the State Plan; and
 - (2) Required to treat an emergency anaphylactic reaction that is caused by an immunization or vaccine;

- (e) Administer immunizations and vaccines pursuant to a written protocol, valid prescription, or physician standing order as required under § 6512 of Title 17 DCMR or the applicable professional practices act within the jurisdiction where services are provided;
 - (f) Administer emergency anaphylactic agents if emergency anaphylactic reaction treatment is deemed appropriate by a delegating physician as set forth in a written protocol, consistent with the requirements set forth under § 6512 of Title 17 DCMR or the applicable professional practices act within the jurisdiction where services are provided;
 - (g) Ensure all written protocols are current and reviewed annually with the delegating physicians, consistent with the requirements set forth under § 6512 of Title 17 DCMR or the applicable professional practices act within the jurisdiction where services are provided;
 - (h) Practice at a pharmacy that is an enrolled DC Medicaid provider in compliance with provider screening and enrollment requirements set forth under Chapter 94 of Title 29 DCMR; and
 - (i) Notify the beneficiary's primary care physician if a flu vaccine or a vaccine that is not covered under the VFC Program is administered to a child under nineteen (19).
- 2715.4 Except for flu vaccines, Medicaid reimbursement shall not be available if an immunization or vaccine that is covered under the VFC Program is administered to a child.
- 2715.5 Pharmacists shall comply with the requirements of § 6512 of Title 17 DCMR, as described in § 2715.3, which are under the purview of the Department of Health in accordance with Chapter 19 of Title 22-B DCMR.
- 2715.6 DHCF shall reimburse administration services described in § 2715.2 to a pharmacy in which the pharmacist, described in § 2715.3, administers the services.
- 2715.7 DHCF shall reimburse pharmacist-administered immunizations, vaccines, and emergency anaphylaxis agents in accordance with this section as follows:
- (a) DHCF shall provide separate administration fees for injectable products and for nasal products;
 - (b) Pharmacies receiving reimbursement for administration of immunizations, vaccines, and emergency anaphylaxis agents shall not receive the professional dispensing fee, described in §§ 2710 – 2711 of this chapter;

- (c) The fees may be updated annually, and changes to the fee shall be published on the Medicaid website at www.dc-medicaid.com, subject to the requirements governing the Medicaid Fee Schedule as set forth under § 988 of Title 29 DCMR; and
- (d) DHCF shall reimburse the pharmacy separately for the cost of the immunization, vaccine, and/or anaphylaxis agent, in accordance with the requirements set forth under the State Plan, Attachment 4.19-B (“Payment for Services”), Part 1, pages 2 through 3c of the State Plan and the requirements of this chapter.

Section 2799, DEFINITIONS, is amended to read as follows:

2799 DEFINITIONS

2799.1 For the purposes of this chapter, the following terms shall have the meanings ascribed:

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.

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

Administer - The direct application of a prescription drug to the body of the beneficiary by injection, inhalation, ingestions, or any other means to the body of a patient.

Administration fee - A fee reimbursed to a pharmacy that employs or contracts a pharmacist that directly applies an immunization, vaccine, or emergency anaphylaxis agent by injection or inhalation to the body of a Medicaid beneficiary.

Anaphylaxis - A rapidly progressing, life-threatening allergic reaction.

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

Emergency anaphylaxis agent - A medication used to treat anaphylaxis caused by the administration of an immunization or vaccine.

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.

Immunization - The act of inducing antibody formation, thus leading to immunity.

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 - This program was created pursuant to the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508; 104 Stat. 1388 (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 DHCF to manage pharmacy networks, provide drug utilization reviews, outcome management and disease management.

Vaccination - Administration of any antigen in order to induce immunity; is not synonymous with immunization since vaccination does not imply success.

Written protocol - A specific written plan for a course of medical treatment containing a written set of specific directions created by the physician for one or more patients, consistent with requirements set forth under Chapter 65 of Title 17 DCMR.

X-DEA number - A unique identification number (x-number) assigned by the Drug Enforcement Administration under the Drug Addiction Treatment Act of 2000 (Pub. L. 106-310; 114 Stat. 1101) in order to prescribe or dispense buprenorphine/naloxone drug preparations.