

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 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. & 2016 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) (2012 Repl.)), hereby gives notice of the adoption a new Chapter 100 of Title 29 (Public Welfare) of the District of Columbia Municipal Regulations (DCMR), entitled, "Lactation Services."

This rule sets forth the services covered under Medicaid to promote breastfeeding of infants, including lactation consultation education and support, breast pumps and lactation supplies, and banked donor milk. These lactation services are included in "pregnancy-related services" under 42 CFR § 440.210, durable medical equipment under Section 2110(a)(12) of the Social Security Act, and Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services pursuant to Section 1905(a)(4)(B) of the Social Security Act, respectively. Extensive research studies have documented many short-term and long-term benefits of breastfeeding for both the nursing infant and mother, and the Centers for Medicare and Medicaid Services (CMS) encourages States to increase access to lactation services. The U.S. Preventive Services Task Force (USPSTF) specifically recommends coordinated interventions throughout pregnancy, birth, and infancy to increase breastfeeding initiation, duration, and exclusivity. This rule supports breastfeeding as the optimal way to feed infants. Additionally, this rule sets standards for Medicaid participation and identifies health care practitioners eligible for reimbursement of lactation services. DHCF projects an increase in aggregate expenditures of approximately \$598,923 in FY 2017.

An initial Notice of Proposed Rulemaking was published in the *D.C. Register* on September 2, 2016 at 63 DCR 011169. No comments were received and no substantive changes have been made. One technical change has been made to Subsection 10001.7 to correct the citation for the qualifications of a registered lactation consultant that is employed by or has a contract with a Federally Qualified Health Center (FQHC).

The Director has adopted these rules as final on January 17, 2017, and they shall become effective on the date of publication of this rulemaking in the *D.C. Register*.

Title 29 DCMR, PUBLIC WELFARE, is amended by adding a new Chapter 100 as follows:

CHAPTER 100 LACTATION SERVICES

10000	General Provisions
10001	Lactation Consultation, Education, and Support
10002	Breast Pumps and Lactation Supplies

10003 **Banked Donor Milk**
10004 **Records**
10005 **Reimbursement**
10006 **Audits and Reviews**
10099 **Definitions**

10000 GENERAL PROVISIONS

10000.1 These rules establish the standards and conditions of reimbursement of lactation services under the District of Columbia Medicaid Program.

10000.2 The provisions of this chapter governing conditions of participation for providers of lactation services shall be in support and furtherance of breastfeeding as the optimal way to feed infants.

10000.3 The following lactation services, included in this chapter, shall be consistent with the regulations set forth herein:

- (a) Lactation consultation, education, and support;
- (b) Breast pumps and lactation supplies; and
- (c) Banked donor milk.

10001 LACTATION CONSULTATION, EDUCATION, AND SUPPORT

10001.1 Lactation consultation, education, and support shall mean evaluation of the mother and infant's overall breastfeeding readiness, education on proper breastfeeding techniques, education on the proper use of a breast pump, and delivery of other necessary information and assistance to enhance breastfeeding.

10001.2 Lactation consultation, education, and support shall be reimbursed by the Department of Health Care Finance (DHCF) under the "pregnancy-related services" benefit, subject to any requirements set forth in the State Plan, implementing rules, and any subsequent amendments thereto.

10001.3 Lactation consultation, education, and support shall be covered for Medicaid-eligible women as follows:

- (a) One (1) prenatal visit; and
- (b) Up to six (6) visits during the sixty (60) day postpartum period. The sixty (60) day postpartum period shall be defined as beginning on the last day of pregnancy and extending through the end of the calendar month in which the sixtieth (60th) day after the end of the pregnancy falls.

- 10001.4 Reimbursable lactation consultation, education, and support may be provided in a clinic, physician's office, freestanding birth center, or in the home, by practitioners set forth under Subsection 10001.5.
- 10001.5 The following practitioners shall deliver lactation consultation, education, and support services in the settings described in Subsection 10001.4:
- (a) A certified nurse mid-wife, licensed pursuant to the District of Columbia Health Occupations Revision Act of 1985 (HORA), effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code §§ 3-1201 *et seq.* (2012 Repl. & 2015 Supp.)), Chapter 58 (Nurse-Midwives) of Title 17 of the District of Columbia Municipal Regulations (DCMR), and who demonstrates current certification by the International Board of Lactation Consultant Examiners (IBLCE) to deliver lactation consultation, education, and support; or
 - (b) A registered lactation consultant, who demonstrates current certification by the IBLCE to deliver lactation consultation, education, and support.
- 10001.6 In order for a provider under Subsection 10001.5 to receive Medicaid reimbursement, each provider shall comply with all provider screening and enrollment requirements set forth under Chapter 94 (Medicaid Provider and Supplier Screening, Enrollment, and Termination) of Title 29 DCMR. Additionally, a registered lactation consultant shall meet the following requirements, unless Subsection 10001.7 applies:
- (a) Deliver lactation consultation, education, and support only when the services are ordered and/or prescribed by a physician, nurse practitioner, or certified nurse midwife who is licensed pursuant to HORA and corresponding rules, and is screened and enrolled in accordance with Chapter 94 of Title 29 DCMR;
 - (b) Submit a copy of the order or prescription for lactation consultation, education and support with each claim that is submitted for Medicaid reimbursement; and
 - (c) Complete an orientation session on billing provided by DHCF or its agent.
- 10001.7 If a registered lactation consultant who meets the qualifications in Section 10001.5(a) is employed by or has a contract with a Federally Qualified Health Center (FQHC) to deliver lactation consultation, education, and support, and the FQHC submits claims for reimbursement to DHCF for those services in accordance with Chapter 45 (Medicaid Reimbursement for Federally Qualified Health Centers) of Title 29 DCMR, the registered lactation consultants shall not bill DHCF separately for those services.

10002 BREAST PUMPS AND LACTATION SUPPLIES

- 10002.1 Breast pumps described under Subsection 10002.3 and lactation supplies described under Subsection 10002.4 are reimbursable for mothers with infants under “durable medical equipment,” subject to any requirements set forth in the District of Columbia State Plan for Medical Assistance (State Plan), § 996 of Title 29 DCMR, and any subsequent amendments thereto.
- 10002.2 Breast pumps and lactation supplies described under Subsections 10002.3 and 10002.4 shall be reimbursable if:
- (a) The criteria set forth under Subsection 10002.3 is met;
 - (b) Prescribed by one of the following providers that has been screened and enrolled pursuant to Chapter 94 (Medicaid Provider and Supplier Screening, Enrollment, and Termination) of Title 29 DCMR and has a treatment relationship with the beneficiary or infant:
 - (1) A physician licensed pursuant to HORA and corresponding rules;
 - (2) A nurse practitioner licensed as an advanced practice registered nurse pursuant to HORA and corresponding rules; or
 - (3) A certified nurse mid-wife licensed as an advanced practice registered nurse pursuant to HORA and corresponding rules; and
 - (c) The infant is between the age of zero (0) and twelve (12) months, unless DHCF or its agent grants prior authorization when an infant is older than twelve (12) months.
- 10002.3 The following breast pumps are available to beneficiaries in accordance with Subsection 10002.2, subject to the following additional requirements:
- (a) Hospital grade, or multi-user, electric pump only available for rental through prior authorization under the following circumstances:
 - (1) A mother and infant are separated due to illness;
 - (2) A mother is unable to feed directly from the breast due to congenital anomalies;
 - (3) A mother is unable to feed directly from the breast due to the prematurity of the baby;
 - (4) A mother requires induced lactation;
 - (5) A mother requires re-lactation;

- (6) An infant is adopted; or
- (7) A mother or infant has other medical or psychological conditions that preclude effective feeding at the breast.

(b) Individual electric breast pump for a mother who needs to maintain lactation because of separation from the infant on a regular basis, such as being employed.

(c) Manual breast pump for a mother who needs to occasionally express milk.

10002.4 Subject to the requirements under Subsection 10002.2, the following lactation supplies shall be reimbursed by DHCF:

- (a) A maximum of two (2) breast pump kits, including tubing, valves, flanges, and collection bottles;
- (b) Nipple shields; and
- (c) Supplemental feeding tubes/devices and syringes.

10003 BANKED DONOR MILK

10003.1 Medicaid-reimbursable banked donor milk shall be provided on an outpatient basis for Medicaid-eligible mothers with infants, and shall be provided in accordance with the following requirements:

- (a) The infant is between the age of zero (0) and twelve (12) months, unless DHCF or its agent grants prior authorization when an infant is older than twelve (12) months;
- (b) The infant requires banked donor milk due to the following reasons:
 - (1) Banked donor milk is necessary for the infant to thrive because the infant is fragile, preterm, or is medically compromised, such as having a diagnosis of formula intolerance, metabolic conditions, or genetic conditions requiring human milk; and
 - (2) The mother cannot breastfeed due to illness, death, surgery, chronic condition, or drug or medication use that is contraindicated for breastfeeding;
- (c) The requesting physician is the infant's treating physician and has documented medical necessity in accordance with Subsection 10003.2 of this chapter;

- (d) The requesting physician has discussed with the parent or guardian the benefits and risks of using banked donor milk, including infectious disease, freshness, effects of pasteurization, nutrients, and growth factors;
- (e) The requesting physician has addressed with the donated human milk bank donor screening, pasteurization, milk storage, and transport of the donated milk;
- (f) The requesting physician has provided an informed consent form that the parent or guardian has signed and dated, and indicates that the risks and benefits of using banked donor milk have been discussed with them; and
- (g) The banked donor milk is pasteurized, donated by a screened donor, and supplied by a donated human milk bank that meets the following requirements:
 - (1) Is screened and enrolled in Medicaid pursuant to the requirements set forth in Chapter 94 (Medicaid Provider and Supplier Screening, Enrollment, and Termination) of Title 29 DCMR;
 - (2) Is approved by the Human Milk Bank Association of North America (HMBANA) and meets other standards as may be adopted by DHCF;
 - (3) Adheres to guidelines set forth by HMBANA and meets other standards as may be adopted by DHCF; and
 - (4) Transports banked donor milk in a manner that protects the milk from contamination, thawing, and refreezing.

10003.2 The following documentation shall be submitted to DHCF for review and approval in order to determine the medical necessity of banked donor milk:

- (a) A Donated Human Milk Request Form that is:
 - (1) Completed and signed by the treating physician on an initial or continuing request for authorization, and specifies the quantity and time frame; and
 - (2) Completed by the donated human milk bank, and specifies the quantity and time frame;
- (b) The following written documentation from the treating physician to support a finding that banked donor milk is medically necessary for the beneficiary:

- (1) A detailed explanation of why the particular infant cannot survive and grow as expected on any other formula (*e.g.*, elemental, special, or routine formulas or food) or any enteral nutritional product other than donor human milk;
 - (2) A detailed explanation of why donated human milk must be used to correct or ameliorate a documented condition or defect; and
 - (3) Documentation that the infant participated in a clinical feeding trial of an appropriate nutritional product every one hundred eighty (180) days. If the infant is too fragile for a feeding trial, documentation must support the illness that makes the infant too fragile to test; and
- (c) The informed consent that identifies the risks and benefits for the parent or guardian of using banked donor milk.

10003.3 A request for authorization for banked donor milk shall be completed, signed, and submitted to DHCF by the treating physician every ninety (90) days, and shall expire upon the infant's first birthday.

10004 RECORDS

10004.1 Each provider shall maintain complete and accurate records reflecting the specific lactation services ordered and provided to each beneficiary. Additionally, the ordering physician of donated human milk and the donated human milk bank shall each maintain copies of the Donated Human Milk Request form.

10004.2 Each provider shall permit reviews and on-site inspections to be conducted by CMS, its agents, DHCF and its agents to determine provider compliance with all applicable laws.

10004.3 Each provider shall maintain, and make available upon request by authorized federal and local Medicaid personnel, complete financial records covering its operations.

10004.4 All financial and treatment records and information shall be maintained for a period of at least ten (10) years following the date of treatment for which a claim for reimbursement was made or when all audits or investigations have been completed, whichever is longer.

10004.5 Each provider shall comply with the terms of its Medicaid Provider Agreement with respect to the maintenance of all beneficiary and financial records.

10004.6 All medical records shall be maintained in accordance with the Health Insurance Protection and Affordability Act of 1996 (HIPAA), effective August 21, 1996 (Pub. L. 104-191, 110 Stat. 1936) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), enacted under Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub.L. 111-5).

10005 REIMBURSEMENT

10005.1 Each provider shall comply with the requirements set forth in Chapter 14 (Health-Care Assistance Reimbursement) of Title 29 DCMR.

10005.2 DHCF shall establish fees and reimbursement for only those services outlined in Subsections 10001 through 10003. Reimbursement for lactation services shall be made according to the District of Columbia Medicaid fee schedule available online at <http://www.dc-medicaid.com>.

10006 AUDITS AND REVIEWS

10006.1 DHCF shall perform audits to ensure that Medicaid payments are consistent with efficiency, economy, and quality of care and made in accordance with federal and District rules governing Medicaid.

10006.2 Each Provider shall allow access to relevant records and program documentation upon request and during an on-site audit or review by DHCF, other District of Columbia government officials and representatives of the United States Department of Health and Human Services (HHS).

10099 DEFINITIONS

10099.1 When used in this chapter, the following terms and phrases shall have the meanings ascribed:

Breast pump - A device used to extract breast milk from a lactating mother. The following are breast pumps for the purposes of this chapter:

- (a) **Hospital grade electric breast pump** - A breast pump with high levels of suction and pressure that are typically larger and heavier than other breast pumps.
- (b) **Individual electric breast pump** - A breast pump that typically runs on batteries or household current, and is typically lightweight and compact.
- (c) **Manual breast pump** - A breast pump that does not run on electricity and allows the user to produce the suction and control

the pressure exerted from the pump.

Induced lactation - The process of making milk without going through pregnancy and birth.

Nipple shields - A cover which a mother places over her nipple prior to breastfeeding.

Pregnancy-related services - Services that are necessary for the health of the pregnant woman and fetus, or that have become necessary as a result of the woman having been pregnant.

Re-lactation - The process of rebuilding milk supply when it has reduced significantly or is not of sufficient quantity to sustain the baby, after weeks or months of not breastfeeding.

Supplemental lactation aides - a device that allows a breastfeeding mother to supplement the infant with expressed breast milk.