DEPARTMENT OF HEALTH CARE FINANCE

NOTICE OF PROPOSED 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. 744; 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 intent to adopt an amendment to Section 997 of Chapter 9 (Medicaid Program) of Title 29 (Public Welfare) of the District of Columbia Municipal Regulations (DCMR), entitled "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies."

These proposed rules update the guidelines for reimbursement of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) under the District of Columbia Medicaid program, in line with new federal requirements, codified at 42 CFR § 440.70, for DMEPOS provided under the State Plan Home Health services benefit. The new federal requirements include the provision and documentation of a face-to-face encounter with the beneficiary by the ordering health practitioner, as well as clarification regarding the settings in which DMEPOS may be provided under the State Plan Home Health services benefit.

The Director also 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 9, MEDICAID PROGRAM, of Title 29 DCMR, PUBLIC WELFARE, is amended as follows:

Section 997, DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES, is amended as follows:

- The Department of Health Care Finance (DHCF), the single state agency for the administration of medical assistance programs authorized under Titles XIX and XXI of the Social Security Act, shall ensure the provision of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to qualified Medicaid beneficiaries in accordance with the requirements of this section and the D.C. Medicaid DMEPOS Provider/Supplier Billing Manual. All providers/suppliers of DMEPOS shall be enrolled as such by DHCF in accordance with Provider and Supplier Screening and Enrollment regulations and policies and § 996 of Title 29 District of Columbia Municipal Regulations (DCMR).
- DHCF shall ensure that each Medicaid beneficiary retains his/her freedom of choice of DMEPOS providers/suppliers, in accordance with 42 CFR § 431.51.
- In order for a beneficiary to receive DMEPOS, the following requirements shall be met:

- (a) The cost of the item shall be reasonable;
- (b) The item shall be prescribed by a physician or other licensed practitioner of the healing arts operating within the scope of practice allowed under the District of Columbia Health Occupations Revision Act of 1985, as amended, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code §§ 3-1201.01 et seq.) and implementing rules, as well as all other applicable federal and District laws;
- (c) The prescribing clinician shall be enrolled as a provider in the District of Columbia Medicaid Program; and
- (d) The prescribing clinician and DMEPOS provider/supplier shall provide their National Provider Identification (NPI) numbers on the prescription, DMEPOS Request and Prior Authorization Form (Form 719(A)), and claim.
- The prescribing clinician shall ensure that Form 719(A) and any supporting documentation describe the beneficiary's condition and include, at minimum, a description of the following:
 - (a) The diagnosis related to the need for the DMEPOS item;
 - (b) Any complicating medical conditions;
 - (c) The functional abilities and limitations, using assessments based on the standards described in § 997.8;
 - (d) The anticipated duration of the condition;
 - (e) The physical examination findings; and
 - (f) The potential for rehabilitation, if applicable.
- For a beneficiary ages birth through twenty-one (21), who is entitled to the early and periodic screening, diagnosis, and treatment (EPSDT) benefit, covered items shall be limited to DMEPOS that are included within the scope of the definition set forth in Section 1905(r) of the Social Security Act (42 USC § 1396d(r)).
- 997.6 Medicaid reimbursement of DMEPOS shall require prior authorization by DHCF or its designee for the following items:
 - (a) DMEPOS items that exceed specific criteria and/or require prior authorization, as set forth in the D.C. Medicaid Provider/Supplier Billing

Manual and/or D.C. Medicaid Fee Schedule, available online at <u>www.dc-</u>medicaid.com;

- (b) DMEPOS items that are billed using miscellaneous codes or that require manual pricing;
- (c) Items of durable medical equipment (DME) that exceed five-hundred dollars (\$500) in purchase price, unless exempted from the requirement as indicated on the fee schedule;
- (d) Customized equipment; and
- (e) DME, prosthetics, and orthotics, outside of the warranty period, that require repair or replacement.
- 997.7 For items that require prior authorization in order to be reimbursed by Medicaid, as set forth in § 997.6, the following tasks shall be completed:
 - (a) The prescribing clinician, as identified on the prescription provided in accordance with § 997.3(b), shall complete the clinical portion of Form 719(A) and provide the form to the DMEPOS provider/supplier for completion;
 - (b) The DMEPOS provider/supplier shall present the completed Form 719(A), including the corresponding prescription, to DHCF or its designee for approval; and
 - (c) The DMEPOS provider/supplier shall collect and submit supporting documentation and invoices to DHCF or its designee for review and approval.
- 997.8 DHCF or its designee shall use national standards, such as InterQual, to assess the reasonableness and necessity of all DMEPOS that requires prior authorization.
- 997.9 A supplier that delivers a DMEPOS item that is subject to prior authorization, as set forth in § 997.6, before DHCF or its designee has issued a prior authorization for the item shall not receive Medicaid reimbursement for the item.
- 997.10 Except for oxygen and oxygen equipment provided to children, qualified physicians or other practitioners of the healing arts operating within the scope of practice outlined in the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986, as amended (D.C. Law 6-99; D.C. Official Code §§ 3-1201.01 et seq.) and implementing rules, shall review a beneficiary's continued need for any DMEPOS item at least on an annual basis, or as otherwise appropriate based on a beneficiary's condition in order to receive Medicaid reimbursement.

- 997.11 Information set forth in the D.C. Medicaid DMEPOS Provider/Supplier Billing Manual shall govern specific criteria regarding Medicaid reimbursement for the following categories of DMEPOS items:
 - (a) Mobility assistive equipment; and
 - (b) Oxygen and oxygen equipment.
- A DMEPOS provider/supplier shall not provide any new item for which prior authorization is required, as set forth in § 997.6, to a beneficiary until DHCF or its designee has provided a new prior authorization number. If a prior authorization has previously been issued for an item to a different DMEPOS provider/supplier, the current DMEPOS provider/supplier shall include a reference to the original prior authorization number on the Form 719(A) submitted to DHCF or its designee for approval.
- 997.13 DMEPOS Medicaid reimbursement shall be subject to the following standards:
 - (a) DHCF shall establish maximum reimbursement rates for items included under the DMEPOS benefit and shall set forth these rates in the D.C. Medicaid Fee Schedule, available online at www.dc-medicaid.com;
 - (b) All rates for DMEPOS shall be subject to a pricing analysis by DHCF or its designee. The pricing analysis may consider the following:
 - (1) Beneficiary's condition;
 - (2) Brand comparison;
 - (3) Anticipated duration of beneficiary's need for the item;
 - (4) Warranty coverage and conditions;
 - (5) Medicare local coverage and pricing determinations;
 - (6) Pricing under other jurisdictions' Medicaid programs;
 - (7) Usual and customary pricing; or
 - (8) Discounts.
 - (c) For any DMEPOS item that is determined to be covered under the District of Columbia's Medicaid program, but is not included on the D.C. Medicaid Fee Schedule, DHCF shall price the item using the process described in § 997.13(b);

- (d) For a beneficiary enrolled in both Medicare and Medicaid, a DMEPOS provider/supplier shall first bill the Medicare program when providing any item to the beneficiary. If Medicare denies the claim, the provider may then submit the remittance advice along with the claim to DHCF or its designee. Under no circumstances shall a DMEPOS provider/supplier bill a dual eligible beneficiary for any amount not paid by Medicare. Failure to adhere to these requirements may subject the DMEPOS provider/supplier to termination of its Medicaid Provider Agreement;
- (e) If a prescribing clinician or DMEPOS provider/supplier receives a discount for an item ordered for use by a D.C. Medicaid beneficiary, the prescribing clinician and/or DMEPOS provider/supplier shall subtract the amount of the discount from the amount for which reimbursement is sought prior to submitting the claim to DHCF. Failure to comply with the requirements of this paragraph may result in denied claims, temporary suspension of payments, or termination of the Medicaid Provider Agreement;
- (f) A DMEPOS provider/supplier shall provide original documentation reflecting all discounts that apply to the cost of any item provided to a Medicaid beneficiary;
- (g) A DMEPOS provider/supplier shall produce proof of delivery (POD) for all items that are provided to a Medicaid beneficiary, which may include:
 - (1) Receipts that are signed by the beneficiary who requires DMEPOS, or his or her legal representative; or
 - (2) Delivery confirmation.
- (h) Except for items deemed necessary under the EPSDT benefit, the following shall not be covered under the D.C. Medicaid DMEPOS benefit:
 - (1) Replacement of an item while it is still under warranty or before the item meets the associated life expectancy, unless prior authorization is obtained;
 - (2) Ventilators;
 - (3) Acquisition, maintenance, or repair of DME, prosthetic, and orthotic items that do not require prior authorization or are for general use in an institutional provider facility where a beneficiary resides;

- (4) Consumable medical supplies for general or non-beneficiary specific use in an intermediate care facility for individuals with intellectual disabilities (ICF/IID);
- (5) Items solely for comfort and convenience of the beneficiary or his/her caregivers, such as air conditioners;
- (6) Home or vehicle modifications that may be covered under waiver programs operating pursuant to Section 1915(c) of the Social Security Act;
- (7) Rehabilitative equipment, for beneficiaries age twenty-two (22) and up, if designed to bring a beneficiary into an upright position to stimulate vestibular function or balance;
- (8) Items that are not suitable for, or are not primarily used in the home setting, including, but not limited to, car seats and non-rehabilitative strollers; and
- (9) Supplies and other DME items used by personnel of a home health agency during the course of a home visit.
- To be eligible for Medicaid reimbursement, the delivery of DME is subject to the following requirements:
 - (a) DME includes equipment that:
 - (1) Can withstand repeated use;
 - (2) Is primarily and customarily used to serve a medical purpose;
 - (3) Is generally not useful to a beneficiary in the absence of illness or injury;
 - (4) Is appropriate for use in the beneficiary's home; and
 - (5) Is expected to have a useful life of at least three (3) years.
 - (b) For a beneficiary age 0 (zero) through twenty-one (21), DME shall also include equipment used in natural environments;
 - (c) For purposes of this section, for a beneficiary age twenty-two (22) and older, the home shall also include an assisted living center, home for the aged, or other senior living facility;

- (d) DME shall be rented if the beneficiary's medical condition is anticipated to last six (6) months or less. Rental rates shall include costs of maintenance and servicing rented items. Except for fees associated with maintaining and servicing oxygen equipment, DHCF shall not allow payment for maintenance and servicing of a rented item. Any provider/supplier of rental DME seeking Medicaid reimbursement shall adhere to the following:
 - (1) Maintain and repair any DME item(s) being rented to D.C. Medicaid beneficiaries;
 - (2) Accept returns of substandard or unsuitable items; and
 - (3) Provide a replacement item that meets the specifications of the originally prescribed item to the beneficiary and in such a manner as to minimize the burden on the beneficiary.
- (e) The total reimbursement available for DME obtained through rental shall not exceed the purchase price of the item. At the time when rental payments equal the purchase price of the item, the item shall be considered purchased and shall become the property of the beneficiary;
- (f) DME shall be purchased under the following circumstances:
 - (1) If the beneficiary's medical condition is anticipated to last more than six (6) months and the equipment does not require frequent servicing and/or repair; or
 - (2) If the beneficiary's medical condition requires customized equipment.
- (g) DME that is purchased shall become the property of the beneficiary for whom it was prescribed;
- (h) In accordance with § 997.6(e), DHCF, or its designee, shall prior authorize any repairs to purchased equipment. A DME provider/supplier shall be required to submit to DHCF, or its designee, a copy of the warranty for the item needing repair within thirty (30) days of the date of the request for repair;
- (i) When DME is purchased for use by a beneficiary, and is under warranty, the provider/supplier of DME shall be required to pay reasonable charges for maintenance and servicing of the item;

- (j) A DME provider/supplier shall first seek to have a covered item maintained, serviced, or repaired by the manufacturer in accordance with the warranty;
- (k) DHCF shall reimburse a DME provider/supplier for charges related to parts and labor that are not otherwise covered under a manufacturer or supplier warranty;
- (l) When a beneficiary's DME item is undergoing repair, a DME provider/supplier may receive reimbursement for a substitute DME item if prior authorized by DHCF or its designee. Prior authorization of substitute DME items is subject to the following conditions:
 - (1) The substitute DME item must be reasonable and necessary;
 - (2) The frequency of use, or the number of units requested, of the substitute DME item must be consistent with code definitions;
 - (3) The total cost to rent the substitute DME item must not exceed the purchase price; and
 - (4) The substitute DME item shall be prior authorized for a period not to exceed two (2) months, except that substitute DME items provided during repair of customized equipment shall be prior authorized for a period not to exceed six (6) months;
- (m) A DME provider/supplier who is responsible for maintaining, servicing, or repairing a customized item that requires repair or replacement shall perform the following:
 - (1) Obtain an estimated repair time from the manufacturer and provide the information to the Medicaid beneficiary and his/her caregivers; and
 - (2) Provide the beneficiary a substitute DME item with specifications that are as similar to the customized item as possible, if needed or requested, in accordance with prior authorization requirements.
- (n) A DME provider/supplier of substitute DME items shall not continue to bill DHCF for the substitute DME item once the beneficiary receives the repaired or replacement DME item;
- (o) Prior to or at the time of delivery of DME, the DMEPOS provider/supplier shall perform an on-site evaluation of the beneficiary's home, if applicable, in order to verify that the beneficiary can adequately maneuver the item that is provided considering the physical layout, doorway widths

and thresholds, and surfaces. There shall be a written report of this evaluation, and the provider/supplier shall make it available upon DHCF's request. Documentation required under this section shall also be subject to the record keeping requirements of 29 DCMR § 996.9;

- (p) A prescribing clinician shall describe the clinical appropriateness of oxygen therapy by completing CMS Form 484 and submitting to DHCF, or its designee, along with any other required documentation. A beneficiary shall be eligible for oxygen therapy, including portable oxygen therapy, if his or her condition is supported by documentation of diagnosis and laboratory results reflecting any of the following conditions:
 - (1) Severe lung disease, including but not limited to chronic obstructive pulmonary disease (COPD), diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, and widespread pulmonary neoplasm; or
 - (2) Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy, including but not limited to pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache;
- (q) Oxygen therapy shall be subject to the following:
 - (1) An authorization for oxygen therapy shall be valid for twelve (12) months for adults, beneficiaries twenty-two (22) and older, and six (6) months for children, ages zero (0) through age twenty-one (21); and
 - (2) A prescriber of oxygen therapy shall be required to see a beneficiary in person within a thirty (30) day period prior to the start of therapy in order to certify the need for the items/services.
- (r) Oxygen therapy shall not be covered for the following conditions:
 - (1) Angina pectoris in the absence of hypoxemia;
 - (2) Breathlessness without cor pulmonale or evidence of hypoxemia;
 - (3) Severe peripheral vascular disease resulting in clinically evident denaturation in one or more extremities;
 - (4) Terminal illnesses that do not affect the lungs;
 - (5) Treatment of headache, including migraine; and

- (6) Treatment of other health care conditions in which oxygen therapy is determined to be experimental or investigational; and
- (s) Diabetic testing meters shall be limited to those preferred items authorized pursuant to the D.C. Medicaid Diabetic Supplies program.
- The delivery of prosthetics and orthotics shall be subject to the requirements as follows:
 - (a) Prosthetics and orthotics shall include the following:
 - (1) Devices that can replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, as described in § 997.15(b);
 - (2) Breast prostheses, including the surgical brassiere;
 - (3) Leg, arm, back, and neck braces;
 - (4) Artificial legs, arms, including stump cover or harness, where necessary;
 - (5) One pair of conventional eyeglasses or contact lenses furnished subsequent to cataract surgery that included insertion of an intraocular lens;
 - (6) Artificial eyes; and
 - (7) Therapeutic shoes, diabetic shoe inserts, splints, and supports.
 - (b) Coverage of prosthetic and orthotic devices shall include replacements that are required based on a change in a beneficiary's physical condition or consumable nature of the item (e.g., ostomy supplies).
 - (c) Replacement of prosthetic and orthotic devices shall be covered only when prescribed by a clinician meeting the requirements of § 997.3(b).
 - (d) Covered prosthetic and orthotic devices shall not include the following items:
 - (1) Intraocular lenses;
 - (2) Supplies and equipment related to ostomy care that is furnished by home health agency personnel during the course of a home visit; and

- (3) Dental prostheses.
- 997.16 The delivery of supplies shall be subject to the requirements as follows:
 - (a) Supplies shall only include items required for use for the treatment of specific illnesses, injuries, diseases, and/or disabilities and that meet the following:
 - (1) Serve a medical purpose;
 - (2) Are generally not useful to a beneficiary in the absence of illness or injury; and
 - (3) Are appropriate for use in the beneficiary's home.
 - (b) Supplies include, but are not limited to:
 - (1) Lancets;
 - (2) Gloves;
 - (3) Bandages;
 - (4) Enteral products; and
 - (5) Incontinence supplies.
- In addition to all other requirements set forth in this Section, the following requirements must be met in order for a provider to receive Medicaid reimbursement for DMEPOS provided under the Home Health services benefit, in accordance with 42 CFR § 440.70:
 - (a) The DMEPOS shall be provided at the beneficiary's place of residence, which does not include a hospital, nursing facility, or ICF/IID, except for Home Health services in an ICF/IID that are not required to be provided by the facility under 42 CFR § 483.460;
 - (b) The beneficiary's need for the DMEPOS shall be reviewed annually by a physician;
 - (c) The ordering physician or allowed non-physician practitioner, as described in § 997.18, shall:
 - (1) Document that a face-to-face encounter with the beneficiary, related to the primary reason the beneficiary requires medical

- equipment or supplies, occurred no more than six (6) months prior to the start of services; and
- (2) Indicate on the order the name of the practitioner who conducted the face-to-face encounter and the date of the encounter.
- The face-to-face encounter described in § 997.17(c) may be conducted by any of the following practitioners:
 - (a) The beneficiary's physician;
 - (b) A nurse practitioner working in collaboration with the beneficiary's physician;
 - (c) A physician assistant acting under the supervision of the beneficiary's physician; or
 - (d) For beneficiaries admitted to Home Health immediately after an acute or post-acute stay, the attending acute or post-acute physician.

Comments on these rules should be submitted in writing to Claudia Schlosberg, J.D., Senior Deputy Director/Medicaid Director, Department of Health Care Finance, Government of the District of Columbia, 441 4th Street, NW, Suite 900 South, 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.