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 (2012 Repl. & 2013 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 intent to adopt an amendment to Section 996, entitled "Provider of Durable Medical Equipment, Prosthetics and Orthotics Supplies" and add a new Section 997 to Chapter 9 (Medicaid Program), Title 29 (Public Welfare), of the District of Columbia Municipal Regulations (DCMR).

These proposed rules govern access, reimbursement, and limitations on Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) available under the District of Columbia's Medicaid Program.

The U.S. Health and Human Services, Centers for Medicare and Medicaid Services (CMS) maintains an extensive regulatory framework for the delivery of DMEPOS to Medicare beneficiaries. The District of Columbia's Medicaid standards for DMEPOS providers/suppliers rely heavily upon these Medicare requirements; however, until the development of this proposed rulemaking, there has not been a companion set of District regulations to coincide with the CMS service delivery framework. Therefore, the purpose of these rules is to provide a comprehensive regulatory framework for the delivery of DMEPOS to D.C. Medicaid beneficiaries and to align the DMEPOS provider/supplier regulation with the delivery standards and the Medicaid screening and enrollment regulations set forth in Chapter 94 of Title 29 District of Columbia Municipal Regulations.

A multidisciplinary workgroup comprising DHCF policy, program, clinical, and operations personnel developed these regulations during a nine-month process to respond to irregularities seen in DMEPOS utilization and claims data. Similar to the process undertaken to develop the DMEPOS provider standards in 2008, DHCF relied heavily upon Medicare standards when developing the framework to govern the delivery of covered items. By reviewing related cases from the District of Columbia's Office of the Health Care Ombudsman and Bill of Rights, Medicare requirements, and legal standards employed in Virginia and Maryland, the team designed a DMEPOS delivery framework that reinforces quality of service and program integrity. Through this rulemaking, DHCF enhances the regulatory framework for DMEPOS delivery and offers providers/suppliers specific information that is necessary to ensure Medicaid beneficiaries receive necessary items and supplies efficiently.

The Director adopted these rules on March 11, 2014. The Director also gives notice of the intent to take final rulemaking action to adopt these proposed rules in 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, PUBLIC WELFARE, of the District of Columbia Municipal Regulations is amended as follows:

Section 996, PROVIDER OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS AND ORTHOTICS SUPPLIES, is deleted in its entirety and amended to read as follows:

996 PROVIDER OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES

996.1 A provider/supplier of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) shall be governed by Chapter 94 of Title 29 District of Columbia Municipal Regulations (DCMR), the requirements set forth in this section, and the policies and procedures located in the D.C. Medicaid DMEPOS Provider/Supplier Billing Manual provided by the Department of Health Care Finance (DHCF).

996.2 A provider/supplier of DMEPOS shall:

(a) Operate a business that furnishes Medicare-covered items in compliance with all applicable federal and District of Columbia licensure and regulatory requirements;

(b) Be eligible to engage in DMEPOS business once the provider/supplier application has been submitted and approved and the provider/supplier has participated in the Medicaid DMEPOS New Provider/Supplier Training conducted by DHCF and signed a Medicaid Provider Agreement;

(c) Maintain a physical facility that contains space for storing business records, including the supplier's delivery, maintenance, and beneficiary communication records;

(d) Be prohibited from using a post office box as a primary business address;

(e) Be open for business at least forty (40) hours per week in a week that does not contain a holiday a weekday holiday in for which DHCF is closed and be open for business at least thirty-two (32) hours per week in a week that does contain a weekday holiday for which DHCF is closed ;

(f) Maintain a visible sign that states the name of the provider/supplier and the hours of operation;

(g) Permit on-site inspections to be conducted by the Centers for Medicare and Medicaid Services (CMS), its agents, the Department of Health (DOH), DHCF or the agents of DOH or DHCF to determine supplier compliance with all applicable laws;

(h) Promote and maintain a beneficiary's right to privacy when services include fittings of DMEPOS;

(i) Provide patient education on the proper use of services and/or equipment;

(j) Maintain a primary business telephone number listed under the name of the business locally and, if appropriate, a toll-free telephone number for Medicaid beneficiaries. The exclusive use of a beeper number, answering service, pager, telephone line connected to a facsimile machine, or wireless telephone does not satisfy the requirement to have a primary business telephone; and

(k) Submit a document commonly known as a CMS Medicare Supplier Letter issued pursuant to 42 C.F.R. § 424.510 to evidence enrollment of the supplier in the Medicare program.

996.3 A provider/supplier shall maintain, at minimum, comprehensive liability insurance in the amount of three hundred thousand dollars ($300,000.00) and shall provide proof of such insurance to DHCF with its initial application and annually thereafter.

996.4 Each applicant and provider/supplier shall post a continuous surety bond in the amount of fifty thousand dollars ($50,000) against all DMEPOS claims, suits, judgments, or damages including court costs and attorneys' fees arising out of the negligence or omissions of the provider/supplier in the course of providing services to a Medicaid beneficiary or a person believed to be a Medicaid beneficiary. The number of bonds required shall be predicated upon each provider's DME National Provider/Supplier Identification Number (NPI). The DMEPOS provider/supplier categories are as follows:

(a) An existing provider/supplier who is providing services in the D.C. Medicaid program;

(b) A new applicant seeking to become a provider/supplier in the D.C. Medicaid program; or

(c) A provider/supplier who is submitting a new application to change the ownership of an existing enrolled provider, pursuant to § 996.6.

996.5 A provider/supplier shall be required to re-enroll in the Medicaid DMEPOS Program at least once every three (3) years.

996.6 A provider/supplier shall be re-enrolled in the Medicaid DMEPOS Program immediately after any change in business ownership.

996.7 A provider/supplier shall be required to submit required certifications, licenses, permits or any other official information concerning the backgrounds of all employees, licensed or unlicensed, that will interact with Medicaid beneficiaries.

996.8 A provider/supplier shall submit the following information:

(a) A list of all principals of the entity;

(b) A list of all stockholders owning or controlling ten percent (10%) or more of outstanding shares;

(c) The names of all board members and their affiliations;

(d) A roster of key personnel; and

(e) An organizational chart.

996.9 A provider/supplier shall maintain all Medicaid-related records for a period of ten (10) years after the date of service or sale.

996.10 A provider/supplier shall fill orders, fabricate, or fit items from its inventory or by contracting with other companies for the purchase of items necessary to fill the order.

996.11 At the time of product delivery or service, the provider/supplier shall provide the beneficiary with a contact telephone number for assistance.

996.12 A business formed within the geographical boundaries of the District of Columbia seeking enrollment in the District of Columbia Medicaid DMEPOS Program shall be considered an in-state business.

996.13 An in-state business shall submit a business license to DHCF.

996.14 A business formed outside of the geographical boundaries of the District of Columbia is considered an out-of-state business.

996.15 An out-of-state business shall be enrolled in a Medicaid program located within the state of its principal place of business before seeking enrollment in the District Medicaid DMEPOS Program.

996.16 An out-of-state business shall submit all of the following that apply:

(a) A Certificate of Registration to transact business within the District of Columbia issued pursuant to D.C. Official Code § 47-2026.;

(b) The name, business address, and telephone number of its registered agent for the out-of-state business;

(c) Proof of a business address and a business telephone number within the District of Columbia listed under the name of the business for the purpose of providing Medicaid sales and services; and

(d) The Medicaid enrollment provider/supplier number from the state where the out-of-state business' principal place of business is located.

996.17 DHCF shall review an applicant's signed and completed application within thirty (30) business days from its receipt by DHCF.

996.18 DHCF shall return a provider/supplier application package to the applicant when DHCF determines the provider/supplier application package to be incomplete or to contain incorrect information only two (2) times within a twelve (12) month period.

996.19 A DMEPOS Provider/Supplier Enrollment Application may be denied due to any one or more of the following factors:

(a) The applicant has demonstrated an inability to provide services, conduct business, or operate a financially viable entity;

(b) Current availability of similar services or supplies for beneficiaries taking into account geographic location and reasonable travel time;

(c) Number of providers/suppliers of the same type of service or supplies enrolled in the same geographic area;

(d) False representation or omission of any material fact by the applicant in making the application;

(e) Exclusion, suspension, or termination of the applicant from any Medicaid program;

(f) Exclusion, suspension, or termination of the applicant from any program managed by DHCF;

(g) Conviction of the applicant for any criminal offense relating to the delivery of any goods or services for a Medicaid beneficiary;

(h) Conviction of the applicant for any criminal offense relating to fraud, theft, embezzlement, fiduciary responsibility, or other financial misconduct;

(i) Violation of federal or District of Columbia laws, rules, or regulations governing the D.C. Medicaid program by the applicant;

(j) Violation of federal or state laws, rules, or regulations governing a Medicaid program in another state by the applicant;

(k) The applicant has been previously been found by a licensing, certifying, or professional standards board to have violated the standards or conditions relating to licensure or certification of the services provided;

(l) Exclusion, suspension, or termination of the applicant from any Medicare program; or

(m) DHCF has returned a provider/supplier application package to the applicant that is incomplete or contains incorrect information at least two (2) times in the past twelve (12) months.

996.20 An applicant whose provider/supplier application has been denied may resubmit a provider/supplier enrollment application for review and a decision.

996.21 An applicant whose provider/supplier application has been approved to become a D.C. Medicaid DMEPOS Provider is deemed to be enrolled when the applicant has:

(a) Successfully completed the DMEPOS Application that is approved by DHCF;

(b) Signed a District of Columbia Medicaid Provider/Supplier Agreement that has been accepted by DHCF;

(c) Participated in a mandatory Medicaid DMEPOS New Provider/Supplier Orientation conducted by DHCF or its agent; and

(d) Received the D.C. Medicaid DMEPOS Provider/Supplier Billing Manual from DHCF or its agent.

996.22 DHCF may authorize a temporary enrollment of an applicant in the case of a special circumstance when a Medicaid beneficiary requires immediate service, supplies, or equipment, subject to the following limitations:

(a) Temporary enrollment shall be for one specific occurrence involving an identifiable Medicaid beneficiary;

(b) Temporary enrollment shall only be made available one time to a provider/supplier; or

(c) Temporary enrollment may be allowed in situations when the D.C. Medicaid Program is not the primary payer.

996.23 A temporary provider/supplier may become eligible to apply for enrollment in the District of Columbia DMEPOS Program anytime during temporary eligibility or subsequently thereafter.

996.24 DHCF may adopt and include in the provider/supplier agreement other requirements and stipulations that it finds necessary to properly and efficiently administer the D.C. Medicaid Program.

996.25 DHCF may make, or cause to be made, payments for medical assistance and related services rendered to Medicaid beneficiaries only when:

(a) The entity has a current Medicaid Provider/Supplier Agreement in effect with DHCF;

(b) The entity is performing services and supplying goods in accordance with federal and District laws; and

(c) The provider/supplier is eligible to provide the item or service on the date it is dispensed and the beneficiary is eligible to receive the item or service on the date the item or service is furnished.

996.26 Each provider/supplier shall be subject to the administrative procedures set forth in Chapter 13 of Title 29 of the DCMR during the provider's/supplier's participation in the District Medicaid DMEPOS Program.

996.27 In accordance with the requirements set forth in 42 C.F.R. § 455.470, DHCF may impose a temporary moratorium on the enrollment of DMEPOS providers/suppliers.

996.28 Any provider/supplier agreement for DMEPOS in existence on or before May 30, 2008 shall be considered to have expired on December 31, 2009, unless the provider/supplier agreement for DMEPOS contains an expiration date on or before January 1, 2010. Any provider/supplier of DMEPOS whose provider/supplier agreement expires on or before January 1, 2010 is eligible to submit a new provider/supplier agreement pursuant to the rules specified in Section 996 of Title 29 of the DCMR.

A new Section 997 is added to read as follows:

997 DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES

997.1 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).

997.2 DHCF shall ensure that each Medicaid beneficiary retains his/her freedom of choice of DMEPOS providers/suppliers, in accordance with 42 C.F.R. § 431.51.

997.3 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.

997.4 The prescribing clinician shall ensure that Form 719(A) and any supporting documentation describe the beneficiary's condition and include, at minimum:

(a) The diagnosis related to the need for the DMEPOS item;

(b) Any complicating medical conditions;

(c) A description of functional abilities and limitations, using assessments based on the standards described in § 997.8;

(d) The anticipated duration of the condition;

(e) Physical examination findings; and

(f) The potential for rehabilitation, if applicable.

997.5 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 is included within the scope of the definition set forth in Section 1905(r) of the Social Security Act (42 U.S.C. § 1396d(r)).

997.6 DMEPOS shall require prior authorization by DHCF, or its designee, under the following circumstances:

(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 www.dc-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 addition to providing the prescription described in § 997.3(b), the prescribing clinician shall also begin the prior authorization process by completing the clinical portion of Form 719(A) and providing the form to the DMEPOS provider/supplier for completion. The DMEPOS provider/supplier shall then present the completed Form 719(A), including the corresponding prescription, to DHCF or its designee, for approval. The DMEPOS provider/supplier also shall be responsible for collecting and submitting 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 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 before DHCF, or its designee, has completed its review and issued an approval for the item shall not receive payment 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.

997.11 Information set forth in the D.C. Medicaid DMEPOS Provider/Supplier Billing Manual shall govern specific criteria for the following categories of DMEPOS items:

(a) Mobility assistive equipment; and

(b) Oxygen and oxygen equipment.

997.12 In the event that a DMEPOS provider/supplier goes out-of-business, another enrolled DMEPOS provider/supplier that is capable of providing continuous DMEPOS services/items to a beneficiary shall complete a new Form 719(A), include a reference to the original prior authorization number on Form 719(A), and submit the form to DHCF, or its designee. The new DMEPOS provider/supplier shall not provide any new item to a beneficiary until DHCF, or its designee, has provided a new prior authorization number.

997.13 DMEPOS 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 pricing analysis by DHCF, or its designee. The pricing analysis shall consider any, or all, of 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; and/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 manually 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 balance bill a dual eligible beneficiary. 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 be required to 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 be required to produce proof of delivery (POD) for all items that are provided to a Medicaid beneficiary. POD 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 intermediate care facilities for individuals with intellectual disabilities (ICFs/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.

997.14 To be eligible for Medicaid reimbursement, the delivery of DME shall be subject to the following requirements:

(a) DME shall include equipment that:

(1) Can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose;

(3) 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 through 21, DME shall also include equipment used in natural environments;

(c) For purposes of this section, for a beneficiary age twenty-two (220 and older, the home shall also include an assisted living center, home for the aged, or other senior living facility;

(d) DME shall be obtained through rental 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 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 meet the purchase price of the item, the item shall be considered purchased and shall become the property of the beneficiary;

(f) DME shall be obtained through purchase 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, upon receipt of prior authorization by DHCF, or its designee. DHCF, or its designee, shall approve substitute DME items in two (2) month increments, except for substitute DME items provided during repair of customized equipment which shall be approved in six (6) month increments. Approval of substitute DME items is subject to the following conditions:

(1) The substitute DME item is reasonable and necessary;

(2) The frequency of use, or the number of units requested, of the substitute DME item is consistent with code definitions; and

(3) The total cost to rent the substitute DME item does not exceed the purchase price.

(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.

997.15 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.

Section 999.1, DEFINITIONS, is amended by adding the following:

999.1 DEFINITIONS

Consumable – Items that are designed or intended to be used up and then replaced.

Discount - Any form of rebate, wholesale pricing, sale pricing, and similar adjustments to the manufacturer's suggested retail price for an item.

Institutional Facility or Provider - Medicaid enrolled hospitals, nursing facilities, and intermediate care facilities for individuals with intellectual disabilities.

Mobility Assistive Equipment –Ccanes, crutches, walkers, manual wheelchairs, and power wheelchairs.

Natural Environment - Settings that are natural or typical for an infant or toddler of the same age without a disability, which may include the home or community settings.

Comments on these proposed rules shall be submitted in writing to Linda Elam, Ph.D., M.P.H., Senior Deputy Director/State Medicaid Director, Department of Health Care Finance, One Judiciary Square, 441 4th Street, NW, Suite 900S, Washington, DC, 20001, via email at DHCFPubliccomments@dc.gov, online at www.dcregs.dc.gov, or by telephone at (202) 442-9115, within thirty (30) days after the date of publication of this notice in the *D.C. Register*. Additional copies of these proposed rules may be obtained from the above address.