STATE OF MARYLAND
DHMH
Office of Health Services
Medical Care Programs

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Robert L. Ehrlich, Jr., Governor – Michael S. Steele, Lt. Governor – S. Anthony McCann, Secretary

PT 21-05

MARYLAND MEDICAL ASSISTANCE PROGRAM
Medical Supply and Equipment Transmittal No. 57

May 6, 2005

TO: Disposable Medical Supplies/Durable Medical Equipment Providers

FROM: Susan J. Tucker, Executive Director
Office of Health Services

SUBJECT: Proposed Amendments to Disposable Medical Supplies/Durable Medical Equipment Services

NOTE: Please ensure that appropriate staff members in your organization are informed of the contents of this transmittal.

ACTION:
Proposed Regulations

EFFECTIVE DATE:

WRITTEN COMMENTS:
Michele Phinney, 201 West Preston Street
Baltimore, Maryland 21201
Fax 410-333-7667
Call 410-767-6499

PROGRAM CONTACT PERSON
Jane Sacco, Chief
Division of Community Support Services
410-767-1739

COMMENT PERIOD EXPIRES: May 31, 2005

The Maryland Medical Assistance Program proposes to amend Regulations .01 and .04 - .07 under COMAR 10.09.12, Disposable Medical Supplies/Durable Medical Equipment. These amendments set Maryland Medicaid provider reimbursement at 100 percent of the current Medicare fee schedule for items listed on that fee schedule, with the exception of enteral and parenteral supplies. For enteral and parenteral supplies listed on the Medicare fee schedule, Medicaid reimbursement will be set at the greater of 67 percent of the Program's reimbursement rate approved as of July 2004 or 100 percent of the current Medicare rate.

For items not on the Medicare fee schedule, these amendments set reimbursement as follows:

1. Medical supplies - wholesale cost plus 40 percent;

2. Prosthetics – manufacturer's suggested retail price (MSRP) minus 25 percent;

3. Customized equipment - provider's choice of MSRP minus 30 percent or wholesale cost plus 40 percent; and

4. Other equipment – provider's choice of MSRP minus 40 percent or wholesale cost plus 30 percent.

For most rented equipment, these amendments set the monthly rental rate at 10 percent of the purchase price, payable for a maximum of 13 months. For rented equipment that requires frequent and substantial servicing, the amendments provide for monthly rental payments for as long as the equipment remains medically necessary.

In addition to setting reimbursement rates, these amendments remove preauthorization requirements for supplies costing less than $500, equipment costing less than $1,000, orthotics, and enteral and parenteral supplies not exceeding one kit daily. For items that still require authorization pursuant to these amendments, providers will be permitted to request authorization up to 30 days following delivery of the items, beyond which time requests will be denied as untimely. Finally, these amendments provide clarification of existing regulations.

The proposed amendments as printed in the Maryland Register are attached.

Attachment

A. The Department of Health and Mental Hygiene estimates that on an average day, five ventilator-dependent patients determined to be at a nursing home level of care will be served in a chronic hospital under an administrative day rate. Therefore, for FY 2006, the economic impact for this period would be $395.25 ventilator add-on × 365 days × 5 × 1.03 (3 percent inflation) = $742,971. Fifty percent of this amount is State general funds and 50 percent is federal funds.

D. Payments to hospitals will increase by $742,971 as indicated in A, above.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 521, Baltimore, Maryland 21201, or call (410) 767-6499 or 1-877-4MD-DHMH, extension 6499, or fax to (410) 333-7687, or email to regs@dhmh.state.md.us. Comments will be accepted through May 31, 2005.

.10 Billing and Reimbursement Principles.

A. — B. (text unchanged)

C. [Payment] *For patients who are not ventilator-dependent, payment* for approved administrative days shall be the lesser of:

(1) — (2) (text unchanged)

C-1. For patients who are ventilator-dependent, payment for approved administrative days in a hospital shall be the sum of:

(1) An estimated Statewide average Medicaid nursing home payment rate as determined by the Department; and

(2) An estimated Statewide average Medicaid nursing home ventilator add-on rate as determined by the Department.

D. — R. (text unchanged)

S. ANTHONY McCANN
Secretary of Health and Mental Hygiene

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.12 Disposable Medical Supplies and Durable Medical Equipment

Authority: Health-General Article, §§2-104(b), 15-103, 15-105, and 15-129, Annotated Code of Maryland

Notice of Proposed Action

[05-099-P]

The Secretary of Health and Mental Hygiene proposes to amend Regulations **.01** and **.04 — .07** under **COMAR 10.09.12 Disposable Medical Supplies and Durable Medical Equipment**.

Statement of Purpose

The purposes of this action are to: (1) set Maryland Medicaid provider reimbursement at 100 percent of the Medicare fee schedule for applicable items; (2) set reimbursement for other items based on retail price or provider cost, with differential reimbursement for customized equipment; (3) provide straightforward language and administrative simplification; (4) permit providers to request post-service, prepayment authorization for certain items; and (5) reduce the number of items requiring prepayment authorization.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. The proposed action will reduce the Department's expenditures for fee-for-service medical equipment and supplies by $2,600,000 ($1,300,000 general and $1,300,000 federal) during FY2006.

II. Types of Economic Impact.	Revenue (R+/R−) Expenditure (E+/E−)	Magnitude
A. On issuing agency: Medical Assistance Program	(E−)	$2,600,000
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (−)	**Magnitude**
D. On regulated industries or trade groups:	(−)	$2,600,000
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. and D. Under the Department's current reimbursement methodology, expenditures for medical equipment and supplies are expected to be approximately $33,300,000. The cost savings realized from the proposed action will reduce overall expenditures by 7.8 percent, or approximately $2,600,000. Fifty percent ($1,300,000) of this amount is federally funded.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Regulations Coordinator, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 521, Baltimore, Maryland 21201, or call (410) 767-6499 or 1-877-4MD-DHMH, extension 6499, or fax to (410) 333-7687, or email to regs@dhmh.state.md.us. Comments will be accepted through May 31, 2005.

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) "Customary charge" means the uniform amount that the provider charges in the majority of cases for a specific supply or piece of equipment, excluding token charges for charity patients and substandard charges for welfare and other low income patients.

(2) "Customized equipment" means durable medical equipment which is uniquely constructed or substantially modified by the provider from the standard product:

(a) For a specific recipient according to the description and orders of a physician; and

(b) In such a way that the equipment can only be used by the specific recipient.

[(1)] *(3)* (text unchanged)

[(2)] *(4)* "Disposable medical supplies" means consumable or disposable items with minimal or no potential for reuse which are used to serve a medically necessary [and medically appropriate] purpose *and, with the exception of disposable gloves and incontinence supplies, have no practical use in the absence of illness or injury.*

[(3)] *(5)* "Durable medical equipment" means equipment which satisfies all of the following requirements:

(a) (text unchanged)

(b) It is used to serve a medically necessary [and medically appropriate] purpose;

(c) It is appropriate for use in the home[.]; *and*

(d) It has no practical use in the absence of illness or injury.

[(4)] *(6)* "Home" means that place of residence occupied by the recipient, including a [domiciliary-level] *an assisted living* facility, but other than a hospital, nursing facility, or other medical institution.

[(5)] *(7)* — [(9)] *(11)* (text unchanged)

[(10) "Medically appropriate" means an effective service that can be provided taking into consideration the particular circumstances of the recipient and the relative cost of any alternative services which could be used to the same purpose.]

[(11)] *(12)* "Medically necessary" means [directly related to diagnostic, preventive, curative, palliative, or rehabilitative treatment] *that the prescribed or ordered item or service has been determined by the Department to be:*

(a) Directly related to diagnostic, preventive, curative, palliative, or rehabilitative treatment of an illness, injury, or disability;

(b) Consistent with accepted standards of good medical practice;

(c) The most cost efficient service that can be provided without sacrificing effectiveness or access to care; and

(d) Not primarily for the convenience of the recipient, the recipient's family, or the provider.

[(12)] *(13)* — [(13)] *(14)* (text unchanged)

[(14)] *(15)* ["Preauthorization"] *"Prepayment authorization"* means the approval required from the Department or its designee before services can be [rendered] *reimbursed.*

[(15)] *(16)* "Prescriber" means a physician, dentist, podiatrist, or nurse practitioner licensed in the state in which the prescriber's practice is maintained who has examined the recipient [and diagnosed the recipient's medical condition].

[(16)] *(17)* — [(20)] *(21)* (text unchanged)

[(21)] *(22)* Wholesale cost.

(a) "Wholesale cost" means the price paid by the provider to the manufacturer or any other supplier for disposable medical supplies [and] *or* durable medical equipment *after consideration of both primary discounts and secondary volume and prompt payment discounts applicable at the time the manufacturer's invoice is paid.*

(b) (text unchanged)

(c) "Wholesale cost" does not include associated costs[.] *such as:*

(i) Evaluation;

(ii) Assembly by the provider;

(iii) Fitting and adjustment; and

(iv) Delivery to the recipient.

.04 Covered Services.

A. The following medically necessary items are covered when ordered by a prescriber:

(1) [The following disposable] *Disposable* medical supplies used in the home[:].

[(a) Ostomy bags, pouches, seals, discs, adhesives and adhesive removers, colostomy belts (except those used primarily for sports), and irrigation tubing, irrigation bags, and cut-off clamps for the care and treatment of an ostomy,

(b) Noninvasive osteogenesis stimulator including all follow-up care, batteries, repairs, and replacement parts, according to the limitations of Regulation .05E and F of this chapter not to exceed one stimulator for the same fracture,

(c) Catheters (urinary and suction), sterile catheter trays, leg bags, bed bags, irrigation and connecting tubing, and clamps for conditions of permanent urinary incontinence,

(d) Incontinency pants and disposable underpads according to the limitations of Regulation .05B of this chapter,

(e) Skin Care Kit I-A for spinal cord dysfunction which includes sterile 4-inch × 4-inch 8-ply gauze pads — four dozen, sterile cotton tipped applicators — eight dozen packages of two each, and 1-inch porous surgical tape — four rolls,

(f) Skin Care Kit I-B for spinal cord dysfunction which includes sterile 4-inch × 4-inch 8-ply gauze pads — five dozen, sterile ABD pads — two and one-half dozen, sterile elastic 2-ply gauze bandage — two and one-half dozen, 4-inch rubber elastic bandages — two, and sterile tongue blades — two and one-half dozen,

(g) Urinary Incontinence Kit II-A for spinal cord dysfunction which includes condoms — three dozen, 1-inch elastic adhesive bandage — three rolls, liquid skin cement (4 oz.) — one can, and unsterile $^{5}/_{16}$-inch latex tubing — 8 feet,

(h) Urinary Incontinence Kit II-B for spinal cord dysfunction which includes 1-inch elastic adhesive bandage — three rolls, liquid skin cement (4 oz.) — one can, and unsterile catheter extension tubing with connector — four,

(i) Urinary Incontinence Kit II-C for spinal cord dysfunction which includes alcohol wipes — three boxes of 100 each, pH testing paper — one roll of 15 ft., and 1-inch clear hypoallergenic tape — three rolls,

(j) Bowel Incontinence Kit III-A for spinal cord dysfunction which includes bisocodyl suppositories 10 mg — one box of 50, disposable exam gloves — one box of 100, and lubricating jelly — (5 oz.),

(k) Bowel Incontinence Kit III-B for spinal cord dysfunction which includes disposable exam gloves — one box of 100, and lubricating jelly — (5 oz.),

(l) Diagnostic reagent strips and tablets used in testing for ketones and glucose in urine and glucose in blood and finger sticking devices used in obtaining samples for blood glucose testing according to the limitations of Regulation .05C and D of this chapter,

(m) Administration sets for intravenous medication,

(n) Administration sets (tubing), filters, Dravon clamps, and injection caps for parenteral feeding,

(o) Administration sets (bag and tubing), nasogastric tubes, adapters and feeding syringes for enteral feeding,

(p) Enteral nutritional and supplemental vitamins and mineral products given by nasogastric, jejunostomy, or gastrostomy tube in the home.]

(2) Durable medical equipment to be used in the recipient's home [where the usual and customary charge for purchased equipment is equal to or less than $40 or where the usual and customary charge for the rental of the equipment is equal to or less than $10 per month except as listed in Regulation .05 of this chapter];

(3) Repairs to purchased durable medical equipment [when preauthorized by the Program];

(4) — (5) (text unchanged)

(6) Replacement of prostheses once every year for persons under 19 years old and once every 3 years for persons 19 years old or older; *and*

(7) Individually form-fitted support stockings, leg or arm, *used in the recipient's home,* including all fitting, dispensing, and follow-up care, for recipients for whom these supports are medically [indicated] *necessary,* not to exceed two at one time, three times in a 12-month period[, for noninstitutionalized individuals].

B. Documentation Required.

(1) Items in §A of this regulation are covered only when adequate documentation is obtained by the provider and kept on file as part of the permanent business records of the provider. This documentation includes, but is not limited to the:

(a) — (c) (text unchanged)

(d) Make, model, and serial number of the item, *as applicable*; and

(e) Cost of the item to the provider *for individually considered items reimbursed under a cost-plus methodology*.

(2) (text unchanged)

(3) Documentation shall be retained for 6 years [at the location where the item was dispensed. If this location is closed, the documentation shall be retained at the location which is most accessible to the Program] *and be made available upon request by the Department*.

.05 Limitations.

The Program does not cover:

[A. Disposable medical supplies other than those cited in Regulation .04A, B, and E of this chapter;]

[B.] *A.* Incontinency pants and disposable underpads unless:

(1) For medical conditions associated with prolonged urinary or bowel incontinence[,]; and

(2) (text unchanged)

[C. Blood and urine glucose and urine ketone monitor and monitoring supplies as described in Regulation .04B(1) of this chapter exceeding a 100-day supply or the smallest package available if this amount is exceeded;

D. Blood glucose monitor and monitoring supplies unless the following criteria are met:

(1) The patient is an insulin-dependent diabetic; and

(2) There shall be documentation by a physician of poor diabetic control, to include at least one of the following:

(a) Widely fluctuating blood sugars before meal time;

(b) Frequent episodes of insulin reactions; or

(c) Evidence of frequent significant ketosis;]

[E.] *B.* Osteogenesis stimulators unless the following criteria are met:

(1) The use is for noninvasive therapy[,];

(2) The bone fracture is at least 6 months old, except when used for pseudarthrosis[,]; and

(3) (text unchanged)

[F.] *C.* (text unchanged)

[G. Purchase of durable medical equipment when the purchase price for this equipment exceeds $40, with the following exceptions:

(1) Alternating pressure pad with pump,

(2) Apnea monitor,

(3) Bed fracture frame,

(4) Bed mattress,

(5) Bed side rails,

(6) Bed traction stand,

(7) Blood glucose reflectance meters for home use when the following criteria are met:

(a) The patient is an insulin-dependent diabetic;

(b) There shall be documentation by a physician of poor diabetic control, to include at least one of the following:

(i) Widely fluctuating blood sugars before meal time,

(ii) Frequent episodes of insulin reactions, or

(iii) Evidence of frequent significant ketosis;

(c) The patient's physician states that the patient is capable of being trained to use the particular device prescribed in an appropriate manner; and

(d) The device is designed for home rather than clinical use,

(8) Buck's traction,

(9) Burn garments, including all fitting, dispensing, and follow-up care,

(10) Cervical collar, hard,

(11) Commode,

(12) Crutches,

(13) Delivery system (pump and pole assembly) for enteral and parenteral feedings,

(14) Hospital bed,

(15) Individually form-fitted support stockings not to exceed two at one time, three times in a 12-month period, for noninstitutionalized individuals,

(16) IV pole for use with parenteral administration of medication,

(17) Nebulizers and accessories,

(18) Neck brace, 2- and 4-poster,

(19) Orthopedic back braces, rigid type only,

(20) Patient lift,

(21) Pelvic traction,

(22) Positioning splints (hands and feet), in-home use only,

(23) External ambulatory infusion pump with administrative equipment, when usual and customary modes of therapy have been tried and are shown to be unsuccessful or impractical,

(24) Prosthetic devices as described in Regulation .04F of this chapter,

(25) Suction machine,

(26) Transcutaneous electrical nerve stimulator (TENS),

(27) Trapeze, for hospital bed,

(28) Trapeze, free standing,

(29) Walker,

(30) Wheelchair and accessories;

H. Rental of durable medical equipment when the rental charge for this equipment exceeds $10, with the following exceptions:

(1) Alternating pressure pad with pump,

(2) Apnea monitor,

(3) Bed fracture frame,

(4) Bed mattress,

(5) Bed side rails,

(6) Bed traction stand,

(7) Buck's traction,

(8) Commode,

(9) Crutches,

(10) Delivery system (pump and pole assembly) for enteral and parenteral feedings,

(11) Hospital bed,

(12) IV pole for use with parenteral administration of medication,

(13) Patient lift,

(14) External ambulatory infusion pump with administrative equipment, when usual and customary modes of therapy have been tried and are shown to be unsuccessful or impractical,

(15) Suction machine,

(16) Transcutaneous electrical nerve stimulator (TENS),

(17) Trapeze for hospital bed,

(18) Trapeze, free standing,

(19) Walker,

(20) Wheelchair and accessories;]

[I.] *D.* The following durable medical equipment:

(1) Equipment prescribed primarily to provide comfort or convenience, including, but not limited to, emesis basins, posture support chairs, over-the-bed tables[,];

(2) Self-help devices including, but not limited to, grab bars, bath seats and shower stools, and commode seats[,];

(3) Abdominal supports[,];

[(4) Automatic syringe pump for medication administration,]

[(5)] *(4)* Bed boards[,];

[(6) Casts,]

[(7)] *(5)* Corrective shoes[,];

[(8) Elastic ankle supports, knee supports, wristlets, stockings and bandages,]

[(9)] *(6)* Enema bags[,];

[(10)] *(7)* Environmental controls[,];

[(11)] *(8)* Exercise equipment and devices, *unless home use of such equipment is a necessary component of an active physical therapy program;*

[(12)] *(9)* Geriatric chairs[,];

[(13)] *(10)* Heating pads or lamps[,];

[(14)] *(11)* Hot water bottles[,];

[(15)] *(12)* Hydrocollators[,];

[(16)] *(13)* Ice bags[,];

[(17)] *(14)* Knee cages[,];

[(18) Leg braces,]

[(19)] *(15)* Nasal atomizers[,];

[(20) Pediatric braces,]

[(21)] *(16)* Restraints[,];

[(22)] *(17)* Sitz baths[,];

[(23)] *(18)* Soft collars[,];

[(24)] *(19)* Whirlpools[,];

[(25)[*(20)* Whirlpool bath equipment;

[J.] *E.* — [K.] *F.* (text unchanged)

[L. Spinal cord dysfunction supplies exceeding the following:

(1) One kit as described in Regulation .04B(3) and (4) of this chapter per 2 weeks,

(2) One kit as described in Regulation .04B(5), (6), and (7) of this chapter per month, and

(3) One kit as described in Regulation .04B(8) and (9) of this chapter per 3 months;]

[M.] *G.* — [O.] *I.* (text unchanged)

[P.] *J.* Two or more similar pieces of equipment for the same recipient unless [preauthorized] *prepayment authorization has been obtained;*

[Q.] *K.* Replacement of equipment while the item is still under warranty or before having met the Department's life expectancy schedule unless preauthorized *prepayment authorization has been obtained;*

[R.] *L.* — [S.] *M.* (text unchanged)

.06 [Preauthorization] *Prepayment Authorization* Requirements.

A. [Preauthorization] *Prepayment authorization* is required for:

(1) Disposable medical supplies [listed in Regulation .04A and B] with a charge exceeding [$300] *$500*, except as specified in [§§A(2) and (3) and B(1)] *§§B(1) and (4)* of this regulation and durable medical equipment on the approved list of items as individual consideration (I/C);

(2) (text unchanged)

[(3) Osteogenesis stimulators and the preauthorization shall be submitted in writing to include the following:

(a) The form designated by the Department,

(b) The appropriate orthopedic prescription form, and

(c) Appropriate original x-rays or x-ray report;]

[(4)] *(3)* — [(5)] *(4)* (text unchanged)

[(6)] *(5)* Any rental of durable medical equipment after 3 months of rental; [and]

[(7)] *(6)* All repairs to purchased durable medical equipment exceeding $500[.]; *and*

(7) Durable medical equipment with a purchase price of $1,000 or more except as specified in §B(1) and (3) of this regulation.

B. [Preauthorization] *Prepayment authorization* is not required for:

(1) (text unchanged)

(2) Prosthetic devices; [and]

(3) [Durable medical equipment on the approved list of items with both a procedure code and a purchase price under $750.] *Orthotic equipment; and*

(4) Enteral and parenteral supplies not exceeding one unit per day.

C. The prescriber shall submit requests for [preauthorization] *prepayment authorization* in writing, when required, using the [form] *format and procedures* designated by the Department.

D. [Preauthorization] *Prepayment authorization*, when required, may be requested via a facsimile machine to expedite hospital, nursing facility, or other medical institutional discharge or in emergency situations approved by the Program. In this case, the facsimile of the completed [preauthorization] *prepayment authorization* form shall be followed by a written request for [preauthorization] *prepayment authorization* using the original of the form, which shall be submitted immediately to the Department. Providers shall call the Program before making a request via facsimile.

E. Except as provided in §G of this regulation, providers shall submit prepayment authorization requests to the Program not later than 30 days following the first date of service.

[E.] *F.* [Preauthorization] *Prepayment authorization* is issued when:

(1) (text unchanged)

(2) The prescriber submits to the Department adequate documentation demonstrating that the service to be [preauthorized] *authorized* is medically necessary [and medically appropriate]; and

(3) A request for supplies or equipment on the list of approved items, or on the list but without a specified maximum Program price, is accompanied by [one of the following:

(a) For a provider that is the manufacturer of the item documentation of] the manufacturer's suggested retail price[;] or

[(b) For a provider that is not the manufacturer,] an invoice or other documentation of the wholesale cost, *whichever is applicable under Regulation .07 of this chapter.*

[F.] *G.* [Preauthorization] *Prepayment authorization* normally required by the Program is waived when the service is covered and approved by Medicare. However, if the entire or any part of a claim is rejected by Medicare, and the claim is referred to the Program for payment, payment will be made for services covered by the Program only if authorization for those services has been obtained before billing. Non-Medicare claims require [preauthorization] *prepayment authorization* according to §§A — [E.] *F.* of this regulation.

[G.] *H.* The Department is not responsible for any reimbursement to a provider for any service provided which requires [preauthorization] *prepayment authorization* unless [preauthorization] *the authorization* has been granted by the Program.

.07 Payment Procedures.

A. (text unchanged)

B. The provider's billed charges to the Program may not exceed the [lowest price accepted by the provider from any other payor] *provider's customary charge.*

C. (text unchanged)

D. The Department shall pay providers [their charge, subject to §B of this regulation,] *100 percent of the current Medicare rate* for prosthetic devices. *For prosthetic devices for which Medicare has not established a rate, the Department shall pay providers the manufacturer's suggested retail price of the item, less 25 percent.* The payment shall include all fitting, dispensing, and follow-up care.

E. (text unchanged)

F. The Department shall reimburse providers for the purchase of covered services [except as described in §D of this regulation] at the lowest of *the provider's customary charge or:*

[(1) As applicable, either:

(a) For a provider that is also the manufacturer of the item, the manufacturer's suggested retail price less 25 percent; or

(b) For a provider that is not the manufacturer of the item, the wholesale cost to the provider plus 25 percent for durable medical equipment and 50 percent for disposable medical supplies; or

(2) The provider's charge.]

(1) For items for which Medicare has established a rate:

(a) Enteral and parenteral supplies at the greater of 67 percent of the Program's reimbursement rate approved as of July 2004, or 100 percent of the Medicare rate;

(b) All other disposable medical supplies and durable medical equipment at 100 percent of the current Medicare purchase reimbursement rate; and

(c) For medical equipment for which Medicare has established a capped rental rate, the purchase price shall be ten times the current Medicare monthly rental rate; or

(2) For items for which Medicare has not established a rate:

(a) Disposable medical supplies at the provider's wholesale cost plus 40 percent;

(b) Customized equipment at the provider's choice of the manufacturer's suggested retail price minus 30 percent or provider's wholesale cost plus 40 percent; and

(c) Other durable medical equipment at the provider's choice of the manufacturer's suggested retail price minus 40 percent or provider's wholesale cost plus 30 percent.

G. The Department shall reimburse providers for the *monthly* rental of covered services [at $1/13_{th}$ of the purchase price as determined in §F of this regulation. The Department reserves the right to prorate the monthly rental amount for daily rentals] *as follows:*

(1) For items for which Medicare has established a capped rental rate, 100 percent of the current Medicare rental rate;

(2) For items for which Medicare has established a purchase rate only, 10 percent of the current Medicare purchase reimbursement rate; and

(3) For items for which Medicare has not established a rate, 10 percent of the purchase price as determined in §F of this regulation.

H. The Department reserves the right to prorate the monthly rental amount for daily rentals.

[H.] *I.* (text unchanged)

[I.] *J.* The determination to purchase or rent medical equipment shall be based on the prescriber's best faith estimate of length of time the equipment will be needed by the recipient. When the equipment is ordered for:

(1) [13] *12* or more months, the provider shall charge the Program for a purchase, unless:

(a) There is justification to request a rental rather than a purchase of the item, and a request for [preauthorization] *prepayment authorization* is submitted to and approved by the Program[,]; and

(b) The request for [preauthorization] *prepayment authorization* is approved by the Program before the submission of the invoice for the item;

(2) Less than [13] *12* months, the provider shall charge the Program for rental of the item for the duration of the medical necessity except that:

(a) If the equipment is still medically necessary after 12 months of rental, a final thirteenth rental payment shall be made and the equipment is considered purchased by the Program[,]; or

(b) If there is justification to request a purchase rather than a rental of the item, a request for [preauthorization] *prepayment authorization* shall be submitted to the Program and approved by the Program before the submission of the invoice.

K. Medical equipment that is determined by the Department to require frequent and substantial servicing in order to avoid risk to the recipient's health shall be reimbursed at the rental rate in accordance with §G of this regulation until either the equipment is no longer medically necessary or the recipient is no longer eligible for Medical Assistance fee-for-service benefits.

[J.] *L.* Every 90 days during the rental term the provider shall obtain recertification from the prescriber and keep in the provider's records a recertification of continuous medical need that the equipment is still medically necessary [and appropriate].

[K.] *M.* The Department shall review purchase prices and rental charges *for items for which Medicare has not established a rate* at least every 3 years.

[L.] *N.* Once an item has been purchased in full, [and if the Program has contributed in full or in part to the purchase] then title to the equipment shall remain with the Department, and the equipment, after use by the recipient, shall be recovered by the provider. After recovery of the equipment, the provider shall determine the viability of re-

cycling the item and, upon its reissue, bill the Program 75 percent of the Program's original payment.

[M.] *O.* — [O.] *Q.* (text unchanged)

[P.] *R.* The methodology in §§F and G of this regulation shall be used to establish a list of approved items with the corresponding procedure code, maximum allowable reimbursement amount, useful life expectancy, and maximum number allowed. This list shall be made available to the providers for ease of administration of the Program. When the approved list of items contains a price for a procedure code, the Department shall reimburse providers the lesser of the price listed in the approved list or the provider's *customary* charge.

[Q.] *S.* — [R.] *T.* (text unchanged)

S. ANTHONY McCANN
Secretary of Health and Mental Hygiene

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.51 Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Audiology Services

Authority: Health-General Article, §§2-104(b), 15-103, and 15-105, Annotated Code of Maryland

Notice of Proposed Action

[05-098-P]

The Secretary of Health and Mental Hygiene proposes to amend Regulations **.01**, **.05**, and **.06** under **COMAR 10.09.51 Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Audiology Services.**

Statement of Purpose

The purpose of this action is to amend the Maryland Medical Assistance Program's definition for acquisition cost by removing discounts and allowances that are currently reimbursed to the provider. Additionally, limitations have been established for cochlear implant disposable batteries.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. The proposed amendment to remove the discount exemption from the acquisition cost definition will remove the profit collected by the provider of services for the sale of hearing aids to Maryland Medicaid recipients. Removal of this profit will be consistent with other Medicaid regulations which only allow reimbursement of acquisition costs plus an established percentage to cover additional costs to the provider. Hearing aid providers already have an established dispensing fee as well as other fees available to cover additional costs incurred by them such as shipping and handling. This particular amendment may provide $99,000 in total fund savings to the State and federal governments ($49,500 in general funds and $49,500 in federal funds).

II. Types of Economic Impact.	Revenue (R+/R−) Expenditure (E+/E−)	Magnitude
A. On issuing agency::	(E−)	$99,000
B. On other State agencies:	NONE	
C. On local governments:	NONE	
D. On regulated industries or trade groups:	(−)	$99,000
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. and D. The impact of these amendments is based upon a limited provider profit study that was conducted for the payment period of July 1, 2001 through June 30, 2003. A sample of 98 hearing aid cases was evaluated to determine the amount of profit made by the provider for the sale of hearing aids to Maryland Medical Assistance recipients under the EPSDT Program. The findings of this sample are as follows: The Maryland Medical Assistance payment for 98 hearing aids is $290,847. The actual acquisition cost is $242,922. Therefore, the provider profit is $47,925, reflecting about 16.5 percent profit per hearing aid. To apply the findings of the study to the entire Medicaid Program, the department estimated that approximately 500 hearing aids will be purchased through the Maryland Medical Assistance Program during FY 2005 at an estimated cost of $1,200 per aid for a total amount of $600,000. Approximately $99,000 of this amount will be for profit to the providers. Please note that even with this cut the department will continue to reimburse providers a nominal fee of between $106 to $175 per hearing aid for their professional services.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 521, Baltimore, Maryland 21201, or call (410) 767-6499 or 1-877-4MD-DHMH, extension 6499, or fax to (410) 333-7687, or email to regs@dhmh.state.md.us. Comments will be accepted through May 31, 2005.

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) "Acquisition cost" means the actual cost of a product to a provider [before the deduction of discounts and allowances].

(2) — (25) (text unchanged)

.05 Limitations.

[Covered audiology services are limited to:]

A. Covered audiology and postoperative cochlear implant services are limited to:

(1) — (6) (text unchanged)

(7) A maximum of 476 disposable batteries for a cochlear implant per calendar year, purchased every 6 months in quantities of 238 or fewer.

[(7)] *(8)* — [(10)] *(11)* (text unchanged)

B. (text unchanged)

.06 Preauthorization Requirements.

A. The Department shall issue preauthorization for EPSDT Audiology Services when the provider:

(1) (text unchanged)