MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet **PROPOSED OR REPROPOSED** **Actions on Regulations**	**Date Filed with AELR Committee**	**TO BE COMPLETED BY DSD** Date Filed with Division of State Documents Document Number Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 6/8/2018

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	09	51	01-.07

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator
Michele Phinney

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6. Check applicable items:

X- New Regulations

X- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: March 1, 2018.

X- Repeal of Existing Regulations

_ Recodification

_ Incorporation by Reference of Documents Requiring DSD Approval

_ Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

_ Yes **X-** No

8. Incorporation by Reference

_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

_ OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by David Lapp, Assistant Attorney General, (telephone #410-767-5292) on March 6, 2018. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Robert R. Neall

Title	**Telephone No.**
Secretary of Health	410-767-6500

Date

May 3, 2018

Title 10
DEPARTMENT 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

[]

The Secretary of Health proposes to amend Regulations .01, .02, .04—.07 and repeal existing Regulation and adopt new Regulation .03 under COMAR 10.09.51 Audiology Services.

Statement of Purpose

The purpose of this action is to update the language for audiology services and expand audiology services to Maryland Medicaid participants 21 years old or older.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

The Department will expand the audiology program to include Maryland Medicaid participants 21 years old or older. The net total fund expenditure for this expansion is approximately $16,000,000 for FY 19.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	(E+)	$16,000,000
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(+)	$16,000,000
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. The State's budget allocation for Fiscal Year 2019 provides for $16,000,000 in total funds to pay for the expansion of audiology services (hearing aids, cochlear implants) to Maryland Medicaid participants 21 years of age or older.

D. The proposed regulations expand audiology services to include Maryland Medicaid participants 21 years of age or older. Therefore, the Department anticipates that Medicaid participants who are newly eligible for audiology services will seek services from providers in Maryland. As a result, audiology providers will be able to be reimbursed for service and experience a revenue positive impact of $16,000,000.

Economic Impact on Small Businesses

The proposed action has a meaningful economic impact on small business. An analysis of this economic impact follows.
The goal of the proposed action is to expand audiology services to Maryland Medicaid participants who are 21 years old or older. Many of the providers that would be affected by the changes in the regulations are small businesses and would benefit from the intended changes.

Impact on Individuals with Disabilities

The proposed action has an impact on individuals with disabilities as follows:
The proposed action will enable adults who are at risk for or have a hearing impairment to receive hearing aids, cochlear implants, and auditory osseointegrated devices.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through July 9, 2018. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2019
B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?
Yes
C. If 'yes', state whether general, special (exact name), or federal funds will be used:
50 percent General and 50 percent federal funds will be used.

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

G. Small Business Worksheet:

Attached Document:

Title 10

MARYLAND DEPARTMENT OF HEALTH

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

10.09.51.01(3/1/2018)

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

[(1) "Acquisition cost" means the actual cost of a product to a provider.

(2) "At risk for hearing impairment" means the condition of a recipient with a suspect or positive hearing screening or who possesses a risk factor listed on the High Risk Questionnaire as defined in COMAR 10.11.02.03.**]**

(1) "Audiologist" means a professional who is licensed in accordance with Regulation .02 of this chapter who treats hearing disorders and communication problems.

[(3)**]** *(2)* "**[**Audiological**]** *Audiology* assessment" means procedures performed by an audiologist to evaluate and monitor the status of the peripheral auditory system, auditory nerve, and central auditory system, or to establish the site of the auditory disorder by using procedures to quantify and qualify hearing loss by site of lesion, on the basis of perceptual, physiological, or electrophysiological responses to acoustic stimuli, and to describe any communicative disorders.

[(4) "Audiological Center.

(a) "Audiological center" means a multispecialty setting with all necessary equipment for audiological services that operates for the purpose of providing preventive, diagnostic, therapeutic, rehabilitative, and palliative audiological services and other multispecialty services by or under the direction of a licensed practitioner.

(b) "Audiological center" does not include the office of one or more private audiologists regardless of whether the office is eligible or receives reimbursement from third-party payers as an audiological center, if that office provides services only within a single medical specialty or subspecialty.**]**

(3) "Audiology center" is a multispecialty setting with all necessary equipment for audiology services that operates for the purpose of providing preventive, diagnostic, therapeutic, and rehabilitative audiology services, and other multispecialty services by or under the direction of a licensed physician or audiologist, but it does not include the office of one or more private audiologists.

[(5)**]** *(4)* "**[**Audiological**]** *Audiology* services" means services delivered by an audiologist to eligible **[**recipients**]** *participants* in order to diagnose and treat hearing problems **[**identified by an EPSDT screening provider**]**.

[(6) "Audiologist" means a professional who is licensed or certified in accordance with Regulation .02 of this chapter who treats hearing disorders and communication problems.**]**

[(7) "Auditory brainstem response (ABR)" means a series of five or more evoked electrical potentials, generated within the VIIIth cranial nerve and the central auditory pathways in the brainstem, the measurement of which is used for hearing screening and audiological assessment, depending upon the protocol used.**]**

(5) "Auditory osseointegrated device" means a device implanted in the skull that replaces the function of the middle ear and provides mechanical energy to the cochlea via a mechanical transducer.

[(8)**]** *(6)* "**[**Binaural hearing aid**]** *Bilateral*" means **[**separate amplification of,**]** *relating to or involving* both ears **[**simultaneously, which usually means two hearing aids, one for each ear**]**.

(7) "Cochlear implant" means a device that is implanted under the skin that picks up sounds and converts them to impulses transmitted to electrodes placed in the cochlea, restoring some hearing to people with a hearing impairment.

[(9)**]** *(8)* "Department" **[**has the meaning stated in COMAR 10.09.36.01.**]** *means the Maryland Department of Health, the single State agency designated to administer the Medical Assistance Program under Title XIX of the Social Security Act, 42 U.S.C. §1396 et seq.*

(9) "Designee" means any entity designated to act on behalf of the Department.

(10)—(11) (text unchanged)

[(12) "Experimental treatment" means an audiological or hearing aid service that is clinically unproven.**]**

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

[(14)**]** *(13)* "Hearing aid dispenser" means a person who is licensed in accordance with Regulation .02 of this chapter to sell hearing aids or **[**provides**]** *provide* other hearing aid services.

[(15)**]** *(14)* "Hearing aid evaluation" means services provided to a **[**recipient**]** *participant* by an audiologist for determining the benefit of hearing aids and, upon the audiologist's recommendation, the dispensing of hearing aids.

[(16) "Hearing screen" means the completed High Risk Questionnaire, an audiometric, pure tone air conduction test, or tympanometry performed by a physician, or certified nurse practitioner (CNP) to identify the need for a referred hearing screening.

(17) "High Risk Questionnaire" means the list of questions for delineating risk factors to identify neonates and infants who may be at risk for hearing impairment as defined in COMAR 10.11.02.03.

(18) "Infant" means a Maryland resident who is younger than 1 year old.

(19) "Jurisdiction" means a state or the District of Columbia.**]**

[(20)**]** *(15)* "*Maryland* Medical Assistance Program *(Program)*" **[**has the meaning stated in COMAR 10.09.36.01.**]** *means the program of comprehensive medical and other health-related care for indigent and medically indigent individuals.*

[(21)**]** *(16)* (text unchanged)

[(22) "Monaural hearing aid" means a single hearing aid for use in one ear.**]**

(17) "Participant" means an individual who is enrolled with the Department to receive Medical Assistance services.

[(24)**]** *(18)* "Provider" means an audiologist, **[**audiological**]** *audiology* center, or hearing aid dispenser**[**:

(a) Licensed or certified in the jurisdiction in which services are rendered to provide services to recipients;

(b) That meets the requirements of Regulation .03B(3) of this chapter; and

(c) That through an appropriate agreement with the Department has been identified as a Program provider by the issuance of an individual account number.**]** *that is licensed and that, through an agreement with the Department, has been identified as a Program provider by the issuance of a provider number.*

[(25) "Recipient" has the meaning stated in COMAR 10.09.36.01.**]**

(19) "Unilateral" means relating to, involving or affecting one ear.

.02 Licensure [and Certification] Requirements.

A. In order to provide services as an audiologist under this chapter, an audiologist **[**:

(1) Shall**]** *shall* be licensed by the State Board of Examiners for Audiologists, Hearing Aid Dispensers, and Speech-Language Pathologists to practice audiology, as defined in Health Occupations Article, Title 2, Annotated Code of Maryland, or by the appropriate licensing body in the jurisdiction in which the **[**audiological**]** *audiology* services are performed**[**; or

(2) If providing services in a jurisdiction without licensure, shall meet the current standards set forth in 42 CFR §440.110, which is incorporated by reference**]**.

B. (text unchanged)

.03 Conditions for Participation.

A. A provider shall meet all conditions for participation as set forth in COMAR 10.09.36.03.

B. Specific requirements for participation in the Program as an audiologist, audiology center or group, or hearing aid dispenser state are that the provider:

(1) Shall meet the licensure requirements in accordance with Regulation .02 of this chapter; and

(2) May not knowingly employ another person to provide services to Maryland Medical Assistance Program participants after that person has been disqualified from the Program unless prior approval has been received from the Department.

.04 Covered Services.

The Program covers the following *medically necessary* services: **[**for EPSDT recipients who are at risk for hearing impairment**]**:

A. **[**Medically necessary audiological**]** *Audiology* services, as follows:

(1) **[**Audiological**]** *For participants who are at risk or have a hearing impairment, audiology assessments using procedures appropriate for the participant's developmental age and abilities*; *and*

[(2) Electrophysiological measures such as auditory brainstem response (ABR), otoacoustic emissions, and brainstem auditory evoked response for recipients, when one of the following criteria is met:

(a) Failure of the recipient to provide consistent behavioral responses to auditory signals, using procedures appropriate for the recipient's developmental age;

(b) Presence of neuromotor involvement or behavioral disorder, or both, which precludes observation of consistent behavioral responses;

(c) Failure to respond to test signal intensities appropriate for the recipient's developmental age, using developmentally appropriate test procedures;

(d) Presence of inconsistencies in the results of tests administered during the audiological assessment which suggest, but do not define, a hearing impairment;

(e) The Infant High Risk Questionnaire delineates a need; or

(f) A physician refers the infant for the service;**]**

[(3)**]** *(2)* Hearing aid evaluations**[**;**]** and *routine follow-up for participants with an identified hearing impairment, who currently use or are being considered for hearing aids;*

[(4) All services as listed on the Audiology Procedure Code and Fee Schedule, Revision 2010, contained in the Medical Assistance Audiology Provider Manual dated November, 2010; and**]**

B. **[**Medically necessary hearing aid**]** *Hearing amplification* services, as follows:

(1) [Hearing] *Unilateral or bilateral hearing* aids which *are medically necessary and* are:

(a) (text unchanged)

(b) Recommended and fitted by an audiologist in conjunction with written medical clearance from a physician who has performed a medical examination within *the past* 6 months;

(c) Sold on a 30-day trial basis; *and*

(d) Fully covered by a **[**repair**]** *manufacturer's* warranty for a **[**period**]** *minimum* of 2 years, **[**at least 1 year of which is provided by the manufacturer**]** at no cost to the Program; **[**and**]**

[(e) Insured for loss or theft for a period of 2 years per hearing aid; and**]**

(2) Hearing aid accessories and services, as listed below:

(a)—(b) (text unchanged)

[(c) Chest harnesses or belts;

(d) Replacement receivers and cords;

(e) Tone hooks;

(f) Huggie aids;

(g) Protective coverings for hearing aids;

(h) Battery testers;

(i) Dehumidification kits;

(j) Hearing aid stethoscopes;

(k) Other amplification-related items recommended by an audiologist;**]**

[(l)**]** *(c)*—**[**(m)**]** *(d)* (text unchanged)

[(n) Insurance policies as required by §B(1)(c) and (d) of this regulation; and

(o) Extended repair warranties.**]**

(e) Replacement of unilateral or bilateral hearing aids every 5 years when determined to be medically necessary; and

(f) Other hearing aid accessories determined to be medically necessary;

(3) Cochlear implants and related services, as listed below:

(a) Unilateral or bilateral implantation of cochlear implant or implants which are medically necessary including the cost of the device;

(b) Post-operative evaluation and programming of the cochlear implant or implants;

(c) Aural rehabilitation services; and

(d) Repair or replacement of cochlear implant device components subject to the limitations in Regulation .05 of this chapter; and

(4) Auditory osseointegrated device or devices and related services, as listed below:

(a) Unilateral or bilateral implantation of auditory osseointegrated devices which are medically necessary including the cost of the device;

(b) Non-implantable or softband device or devices for participants younger than 5 years old;

(c) Evaluation and programming of the auditory osseointegrated device or devices; and

(d) Repair or replacement, or both of auditory osseointegrated device components subject to the limitations in Regulation .05 of this chapter.

.05 Limitations.

A. Covered audiology **[**and postoperative cochlear implant**]** services, *including hearing aids, cochlear implants and auditory osseointegrated devices* are limited to:

[(1) Recipients under 21 years old who are referred for the service or have had cochlear implant surgery;**]**

[(2)**]** *(1) Unless the time limitation is waived by the Program,* **[**One audiological**]** *one audiology* assessment per year**[**, unless the time limitations are waived by the Program**]**;

(2) The initial coverage of:

(a) Bilateral hearing aids for children younger than 21 years old;

(b) Unilateral hearing aids for participants 21 years old or older unless otherwise approved by the Department or its designee;

(c) Bilateral cochlear implants for participants younger than 21 years old;

(d) Unilateral cochlear implants for participants 21 years old or older;

(e) Bilateral auditory osseointegrated devices for participants younger than 21 years old; and

(f) Unilateral auditory osseointegrated devices for participants 21 years old or older;

(3) **[**One monaural or binaural**]** *Replacement of unilateral or bilateral* hearing **[**aid**]** *aids once* every **[**3**]** *5* years unless the Program approves more frequent replacement;

(4) Replacement of hearing aids, *cochlear implants and auditory osseointegrated device components* that have been lost, stolen, or damaged beyond repair, after all warranties **[**and insurance policies**]** have expired;

(5*)* Repairs and replacements that take place after all warranties **[**and insurance policies**]** have expired;

(6) A maximum of **[**48**]** *76* batteries per **[**recipient**]** *participant* per **[**year**]** *12-month period* for a **[**monaural**]** *unilateral* hearing aid**[**,**]** or *osseointegrated devices, or* **[**96**]** *152* batteries per **[**recipient**]** *participant* per **[**year**]** *12-month period* for **[**a binaural**]** *bilateral* hearing **[**aid,**]** *aids or osseointegrated devices* purchased from the Department not more frequently than every 6 months, and in quantities of **[**24**]** *38* or fewer for a **[**monaural**]** *unilateral* hearing aid, or **[**48**]** *76* or fewer for a **[**binaural**]** *bilateral* hearing aid;

(7) A maximum of **[**476**]** *180* disposable batteries for a *unilateral* cochlear implant *per participant* per **[**calendar year**]** *12-month period* **[**,**]** *or 360 disposable batteries per 12-month period for a bilateral cochlear implant* purchased *not more frequently than* every 6 months, *and* in quantities of **[**238**]** *90* or fewer**[**.**]** *for a unilateral cochlear implant, or 180 or fewer for a bilateral cochlear implant;*

(8) Two replacement cochlear implant component rechargeable batteries per 12-month period *for bilateral cochlear implants, and a maximum of one replacement rechargeable battery for a unilateral cochlear implant*;

(9) Two cochlear implant replacement transmitter cables per 12-month period *for bilateral cochlear implants, and a maximum of one replacement transmitter cable for a unilateral cochlear implant*;

(10) Two cochlear implant replacement headset cables per 12-month period *for bilateral cochlear implants,* and *a maximum of one replacement headset cable for a unilateral cochlear implant*;

(11) Two replacement cochlear implant transmitting coils per 12-month period for bilateral cochlear implants, and a maximum of one replacement transmitting coil for a unilateral cochlear implant;

[(11)**]** *(12)* Charges for routine follow-ups and adjustments which occur more than 60 days after the dispensing of a new hearing aid**[**.**]***;*

(13) A maximum of two unilateral earmolds or four bilateral earmolds per 12-month period for participants younger than 21 years old; and

(14) A maximum of one unilateral earmold or two bilateral earmolds per 12-month period for participants 21 years old or older.

B. Services which are not covered are:

(1)—(3) (text unchanged)

(4) Cochlear implant **[**audiological**]** *audiology* services and external components provided less than 90 days after the surgery or covered through initial reimbursement for the implant and the surgery;

(5) Spare or backup cochlear implant **[**speech processors**]** *components;*

(6) **[**Upgrades to new generation hearing aids, equipment, cochlear implant speech processors, and other components if the existing devices are functional, repairable, and appropriately correct or ameliorate the problem or condition**]** *Spare or back-up auditory osseointegrated device components*;

(7) Replacement of hearing aids, equipment, cochlear implant **[**speech processors**]** *components, and auditory osseointegrated device components* **[**and other components**]** if the existing devices are functional, repairable, and appropriately correct or ameliorate the problem or condition;

(8) (text unchanged)

(9) Repairs to spare or backup hearing aids, *cochlear implants, auditory osseointegrated devices,* equipment, or supplies;

(10) Investigational**[**,**]** *or* experimental**[**, or ineffective**]** services or devices, or both;

[(11) Educationally or socially needed services or equipment;**]**

[(12)**]** *(11)* Replacement of improperly fitted earmold or earmolds unless *the*:

(a)—(b) (text unchanged)

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

.06 Preauthorization Requirements.

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

(1) Meets Program procedures and limitations; and

(2) Submits to the Department adequate documentation demonstrating that the services to be preauthorized are necessary, as stated in COMAR 10.09.23.07.**]**

[B.**]** *A.* The **[**Program**]** *Department* requires preauthorization for the following **[**audiology**]** services:

(1) **[**Certain**]** *All* hearing aids;

[(2) Unlisted hearing aid accessories; and

(3) Unlisted post-cochlear implant external components.**]**

(2) Certain hearing aid accessories;

(3) All cochlear implant devices and replacement components except microphone, transmitter cables and transmitting coils;

(4) All auditory osseointegrated devices; and

(5) Repairs for hearing aids, cochlear implants and auditory osseointegrated components exceeding $500.

[C.**]** *B.* Preauthorization **[**for audiology services expires**]** *is valid:*

(1) For services rendered or initiated within 6 months **[**from the authorized span of time that is issued by the Department and is valid if the recipient is eligible at the time the service is rendered to the recipient.**]** *from the date the preauthorization was issued; and*

(2) If the patient is an eligible participant at the time the service is rendered.

[D.**]** *C.* The following written documentation shall be submitted by the provider *to the Department or its designee* with each *request or preauthorization of* hearing **[**aid that requires preauthorization**]** *aids, cochlear implants, or auditory osseointegrated devices:*

(1) Audiology report documenting medical necessity of the hearing aids, cochlear implants or auditory osseointegrated devices;

[(2) Audiogram; and

(3) Written medical approval by a physician.**]**

(2) Interpretation of the audiogram; and

(3) Medical evaluation by a physician supporting the medical necessity of the hearing aids, cochlear implants or auditory osseointegrated devices within 6 months of the preauthorization request.

.07 Payment Procedures.

[A. Providers shall submit requests for payment for audiology services as stated in COMAR 10.09.36.04.**]**

A. To obtain compensation from the Department for covered services, the provider shall submit a request for payment using the format designated by the Department.

B. Audiology services are reimbursed **[**according to**]** *in accordance with* COMAR 10.09.23.01-1.

[C. Audiologists, audiological centers, and hearing aid dispensers shall charge the Program customary charges, not exceeding those charged to the general public for similar professional services. If the service is free to individuals not covered by Medicaid:

(1) The provider:

(a) May charge the Program; and

(b) Shall be reimbursed in accordance with §B of this regulation; and

(2) The provider's reimbursement is not limited to the provider's customary charge.

D. The provider shall charge the Program the acquisition cost for certain hearing aids, accessories, external cochlear implant accessories, and supplies.

E. The provider shall itemize all hearing aid and external cochlear implant charges including accessories, supplies, shipping or handling, or both, insurance, and warranties.

F. The provider shall submit the request for payment on the form designated by the Department.**]**

C. The provider shall be paid the lesser of:

(1) The provider's customary charge to the general public, unless the service is free to individuals not covered by Medicaid; or

(2) The rate in accordance with the Department's fee schedule.

[G.**]** *D.* The provider may not bill the Department *or participant* for:

(1)—(3) (text unchanged)

[H.**]** *E.* **[**Audiological**]** *Audiology* centers licensed as a part of a hospital may charge for and be reimbursed according to rates approved by the Health Services Cost Review Commission (HSCRC), set forth in COMAR 10.37.03.

[I.**]** *F.* The provider shall refund to the **[**Program**]** *Department* payment for hearing aids, supplies, or both, that have been returned to the manufacturer *within the 30-day trial period*.

[J.**]** *G.* The provider shall give the **[**Program**]** *Department* the full advantage of any and all manufacturer's **[**warranty**]** *warranties* and trade-ins offered on hearing aids, equipment, or both.

[K. The Program shall reimburse for covered services at the lesser of:

(1) The provider's customary charge to the general public unless the service is free to individuals not covered by Medicaid; or

(2) The Program's fee schedule; or

(3) The provider's acquisition cost for the following services:

(a) Hearing aids, accessories, and supplies; and

(b) External cochlear implant accessories and supplies.

L. The Program reserves the right to return to the provider, before payment, all invoices not properly signed, completed, and accompanied by properly completed forms required by the Department.**]**

[M.**]** *H.* Unless preauthorization has been granted by the **[**Program**]** *Department or its designee*, the **[**Program**]** *Department* is not responsible for any reimbursement to a provider for any service provided which requires preauthorization.

[N.**]** *I.* The **[**Program**]** *Department* may not make direct payment to **[**recipients**]** *participants*.

[O.**]** *J.* (text unchanged)

ROBERT R. NEALL

Secretary of Health