TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

TO: REGIONAL ADMINISTRATOR

HEALTH CARE FINANCING ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

5. TYPE OF PLAN MATERIAL (Check One):

☐ NEW STATE PLAN
☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN
☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION:

42 U.S.C. 1396a, 42 CFR Part 440

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 3.1-A, Page 5
Attachment 3.1-B, Page 4
Attachment 3.1-B, Page 5
Limitations on Attachment 3.1-A, Page 14
Limitations on Attachment 3.1-B, Page 14
Limitations on Attachment 3.1-A, Page 18
Limitations on Attachment 3.1-A, Page 18a
Limitations on Attachment 3.1-B, Page 18
Limitations on Attachment 3.1-B, Page 18a
Attachment 4.19-B, Page 3a
Attachment 4.19-B, Page 3d
Attachment 4.19-B, Page 3d.1
Attachment 4.19-B, Page 3g

10. SUBJECT OF AMENDMENT:

Clarifies prescription of durable medical equipment and payment methodologies for hearing aid services, enteral formulae, and durable medical equipment.

11. GOVERNOR'S REVIEW (Check One):

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

☒ OTHER, AS SPECIFIED:

The Governor’s Office does not wish to review the State Plan Amendment.

13. TYPED NAME:

Toby Douglas

14. TITLE:

Director

15. DATE SUBMITTED:

1/7/11

17. DATE RECEIVED:

18. DATE APPROVED:

19. EFFECTIVE DATE OF APPROVED MATERIAL:

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

22. TITLE:
DEC 9, 2011

Gloria Nagle, Ph.D., M.P.A.
Associate Regional Administrator
Division of Medicaid & Children's Health Operations
Centers for Medicare & Medicaid Services, Region IX
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

STATE PLAN AMENDMENT 11-030

Dear Dr. Nagle:

The Department of Health Care Services (DHCS) is submitting State Plan Amendment (SPA) 11-030 in response to the companion letter dated September 12, 2011 received with the approval of SPA 11-012. The enclosed document contains responses to comments in the companion letter. The effective date will be November 1, 2011.

SPA 11-030 addresses comments regarding prescription of durable medical equipment by physicians to beneficiaries receiving home health service as well as reimbursement methodologies for hearing aid services, enteral formulae, and durable medical equipment.

SPA 11-030 has no impact on the Federal budget.

DHCS is submitting the following:

- Revised Limitations on Attachment 3.1-A and 3.1-B, page 14 – clarified that only physicians may prescribe DME for home health services and updated the title description for number 12c.
- Revised Limitations on Attachment 3.1-A and 3.1-B, pages 18-18a – added durable medical equipment to number 12c.
• Added Attachment 4.19-B, pages 3d.1 and 3g – added reimbursement methodologies for hearing aid services and enteral formulae.

DHCS did not notify the Indian Health Programs and Urban Indian Organizations of SPA 11-030. The revisions in SPA 11-030 will not result in a decrease or increase in services, restrict eligibility, change provider qualifications, change reimbursement rates, or methodologies, or otherwise negatively impact Tribes, Indian Health Programs, or Urban Indian Organizations.

If you have any questions regarding the information provided, please contact Ms. Vickie Orlich, Chief, Medi-Cal Benefits and Waiver Analysis Division, at (916) 552-9400.

Sincerely,

Toby Douglas
Director

Enclosures

cc: Donald A. Novo
Division of Medicaid and Children’s Health Operations
San Francisco Regional Office
Centers for Medicare and Medicaid Services
90 Seventh Street, Suite 5-300(5W)
San Francisco, CA 94103

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Health Care Policy
Department of Health Care Services
P.O. Box 997413, MS 4000
Sacramento, CA 95899-7413

Vickie Orlich, Chief
Benefits and Waiver Analysis Division
Department of Health Care Services
1501 Capitol Avenue, MS 4600
P.O. Box 997417
Sacramento, CA 95899-7417
The Centers for Medicare and Medicaid Services (CMS) sent a companion letter with the approval of California State Plan Amendment (SPA) 11-012. The Department of Health Care Services (DHCS) originally submitted the SPA to limit hearing aid benefits at $1,510 per beneficiary per year. CMS’s review of SPA 11-012 included a same page coverage review of the submitted pages, as well as a review of the reimbursement methodologies for services listed on the same page. Based on the review, CMS identified additional issues that are not in compliance with current regulations, statutes, and CMS guidance.

**DME Section in Attachment 3.1-A and 3.1-B**
The durable medical equipment (DME) section that is listed on Attachment 3.1-A and 3.1-B indicates that DME is “covered when prescribed by a licensed practitioner.” The regulations at 42 CFR 440.70(a)(2) requires that home health services (including DME) be ordered by a physician as part of a written care plan. The State should amend the State Plan to indicate that only physicians can prescribe DME.

**State’s Response:** DHCS is submitting Limitations on Attachments 3.1-A and 3.1-B to amend number 7c.2 to clarify that only physicians may prescribe DME for beneficiaries receiving home health services. This is consistent with State regulations. In addition, DHCS is adding DME to number 12c to clarify that DME is also available to beneficiaries who are not receiving home health services.

**Payment Methodologies**
The coverage provisions for Hearing Aids and Enteral Formulae are listed in page 14 of Limitation to Attachment 3.1-A submitted under SPA 11-012. Please identify where in Attachment 4.19-B the reimbursement methodologies are described for these services. If the payment methodology is described on page 20a of Attachment 4.19-B of the current State Plan, please amend the State Plan to include the effective date of the fee schedule and the specific URL address for the fee schedule (instead of the DHCS Medi-Cal home page).

**State’s Response:** The most appropriate location for the reimbursement methodologies for hearing aids and enteral nutrition is in Attachment 4.19-B. DHCS has amended 4.19-B to list the reimbursement methodology for hearing aid services on page 3d and enteral formulae on page 3d.1. The methodologies, effective dates, and statutory references also appear on the accompanying Reimbursement Methodology Table on page 3g.

**Payment Methodology for DME**
The payment methodology for durable medical equipment found in pages 3a – 3f of Attachment 4.19-B was last updated in June 2007. Please confirm whether this language is still accurate.

**State’s Response:** DHCS confirms that the language for the payment methodology for durable medical equipment updated June 2007 is still accurate.
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| 12c Prosthetic and orthotic appliances, durable medical equipment, and hearing aids. | Prosthetic and orthotic appliances are covered when prescribed by a physician or podiatrist. Stock shoes (conventional or orthopedic) are covered when at least one of the shoes is to be attached to a prosthesis or brace. Orthopedic modifications to stock shoes are also covered. Prosthetic eyes are covered when prescribed by a physician or other licensed practitioner performing within his or her scope of practice. Durable medical equipment is covered when prescribed by a licensed practitioner. See 7c.2. Prior authorization is required when the purchase price is more than $100. Prior authorization is required for rental or repair when the total cost is more than $50. Hearing aids are covered only when supplied by a hearing aid dispenser upon the prescription of an otolaryngologist, or the attending physician where there is no otolaryngologist available. Loaner aids, during repair periods covered under guarantee, are not covered. Replacement batteries are not covered. Prior authorization is required for prosthetic eyes and most prosthetic eye services. Replacement of hearing aids that are lost, stolen, or irreparably damaged due to circumstances beyond the beneficiary's control is not included in the $1,510 maximum benefit cap. Authorization for hearing aids may be granted only when tests reveal an average loss of 35 dB or greater, or if the difference between the level of 1,000 Hertz and 2,000 Hertz is 20 dB or more. The hearing loss need only be 30 dB, and speech communication is effectively improved or the need for personal safety is met. | Prior authorization is required when the purchase price is more than $100. Prior authorization is required for rental or repair when the total cost is more than $50. Hearing aid benefits are subject to a $1,510 maximum cap per beneficiary per fiscal year. Hearing aid benefits include hearing aids and hearing aid supplies and accessories. The following are exempted:  
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- Beneficiaries under the Early and Periodic Screening Diagnosis and Treatment Program. |
### Limitations on Attachment 3.1-B

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| 12c Prosthetic and orthotic   | - Beneficiaries who are receiving long-term care in a licensed skilled nursing facility or intermediate care facility (NF-A and NF-B).  
                                | appliances, **[durable medical equipment](https://www.example.com)**, and hearing aids (continued). | Prior authorization is required for low vision devices when the billed amounts are over $100 and for contact lenses when medically indicated for conditions such as aphakia, keratoconus, anisometropia, or when facial pathology or deformity preclude the use of eyeglasses. Prior authorization is required for ophthalmic lenses and frames that cannot be supplied by the fabricating optical laboratory. |
| 12d Eyeglasses and other eye   | Covered as medically necessary on the written prescription of a physician or an optometrist under this state plan only for the following beneficiaries: | - Prior authorization is required for emergency service. |
| appliances                     | 1. Pregnant women if eyeglasses or other eye appliances are part of their pregnancy-related services or for services to treat a condition that might complicate the pregnancy.  
                                | 2. Individual who is an eligible beneficiary under the Early and Periodic Screening Diagnosis and Treatment Program.  
                                | 3. Individual who is receiving long-term care in a licensed skilled or intermediate care facility (NF-A and NF-B). Services would be provided in an FQHC or RHC if an NF-A or NF-B resident is a patient of the clinic.  
                                | 4. Individual who is receiving long-term care in a licensed intermediate care facility for the developmentally disabled (ICF-DD) including ICF-DD Habilitative and ICF-DD Nursing. | **Coverage is limited to medically necessary services** |
| 13a Diagnostic services        | Covered under this state plan only for EPSDT program                                | - 18a -                                                                                                      |
| 13b Screening services         | Covered under this state plan only for EPSDT program                                |                                                                                                              |
| 13c Preventive services        | Covered under this state plan only for EPSDT program and for pregnant/postpartum Medi-Cal recipient |                                                                                                              |

**TN No. 41-012-11-030**  
Supersedes TN No. 09-001 11-012  
Approval Date: ______________________  
Effective Date: 11/1/2011  
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• Beneficiaries receiving contracted managed care with Senior Care Action Network (SCAN) and AIDS Healthcare Foundation. | Prior authorization is required for low vision devices when the billed amounts are over $100 and for contact lenses when medically indicated for conditions such as aphakia, keratoconus, anisometropia, or when facial pathology or deformity preclude the use of eyeglasses. Prior authorization is required for ophthalmic lenses and frames that cannot be supplied by the fabricating optical laboratory. |
| 12d Eyeglasses and other eye appliances              | Covered as medically necessary on the written prescription of a physician or an optometrist under this state plan only for the following beneficiaries:  
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| 13a Diagnostic services                              | Covered under this state plan only for EPSDT program                               |                                            |
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<td>7c.2 Durable medical equipment</td>
<td>For home health services, covered when prescribed by a licensed physician practitioner. DME commonly used in providing SNF and ICF level of care is not separately billable. Common household items are not covered.</td>
<td>Prior authorization is required when the purchase exceeds $100. Prior authorization is required when price, repairs, maintenance, or cumulative rental of listed items exceeds $25, except that the provision of more than two “H” oxygen tanks in any one month requires prior authorization. Purchase or rental of “By Report” (unlisted) items are subject to prior authorization regardless of purchase price. Authorization shall be granted only for the lowest cost item that meets medical needs of the patient.</td>
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<td>Covered only when supplied by a pharmacy provider upon the prescription of a licensed practitioner within the scope of his or her practice. Enteral Formulae commonly used in providing SNF and ICF level of care is not separately billable. Common household items (food) are not covered.</td>
<td>Prior authorization is required for all products. Authorization is given when the enteral formulae is used as a therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food. Dietary supplements or products that cannot be used as a complete source of nutrition are considered non-benefits, except that the program may deem such a product a benefit when it determines that the use of the product is neither investigational nor experimental when used as a therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions.</td>
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TN No. **41-012-11-030**  
Supersedes TN No. **09-001 11-012**  
Approval Date: ___________________________  
Effective Date: **11/1/2011**  

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TN No. 11-030  
Supersedes TN No. 11-012  
Approval Date: __________________________  
Effective Date: 11/1/2011
<table>
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<th>PROGRAM COVERAGE**</th>
<th>PRIOR AUTHORIZATION OR OTHER REQUIREMENTS</th>
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<tr>
<td>7c.2 Durable medical equipment</td>
<td>For home health services, covered when prescribed by a licensed physician practitioner. Common household items are not covered. DME commonly used in providing SNF and ICF level of care is not separately billable.</td>
<td>Prior authorization is required when the purchase exceeds $100. Prior authorization is required when price, repairs, maintenance, or cumulative rental of listed items exceeds $25, except that the provision of more than two “H” oxygen tanks in any one month requires prior authorization. Purchase or rental of “By Report” (unlisted) items are subject to prior authorization regardless of purchase price. Authorization shall be granted only for the lowest cost item that meets medical needs of the patient.</td>
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<td>7c.4 Enteral Formulae</td>
<td>Covered only when supplied by a pharmacy provider upon the prescription of a licensed practitioner within the scope of his or her practice. Enteral Formulae commonly used in providing SNF and ICF level of care is not separately billable. Common household items (food) are not covered.</td>
<td>Prior authorization is required for all products. Authorization is given when the enteral formulae is used as a therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food. Dietary supplements or products that cannot be used as a complete source of nutrition are considered non-benefits, except that the program may deem such a product a benefit when it determines that the use of the product is neither investigational nor experimental when used as a therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions.</td>
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* Prior authorization is not required for emergency services. ** Coverage is limited to medically necessary services.
### STATE PLAN CHART

Limitations on Attachment 3.1-A

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TN 11-030
Supersedes
TN 11-012

Approval date: ________________

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1. The methodology utilized by the State Agency in establishing reimbursement rates for durable medical equipment as described in State Plan Attachment 3.1-A, paragraph 2a, entitled “Hospital Outpatient Department Services and Organized Outpatient Clinic Services”, and Paragraph 7c.2, entitled “Home Health Services Durable Medical Equipment”, will be as follows:

(a) Reimbursement for the rental or purchase of durable medical equipment with a specified maximum allowable rate established by Medicare, except wheelchairs, wheelchair accessories, wheelchair replacement parts, and speech-generating devices and related accessories, shall be the lesser of the following:

(1) The amount billed in accordance with California Code of Regulations, Title 22, section 51008.1, entitled “Upper Billing Limit”, that states that bills submitted shall not exceed an amount that is the lesser of the usual charges made to the general public or the net purchase price of the item (as documented in the provider’s books and records), plus no more than a 100 percent mark-up. (Refer to Reimbursement Methodology table at page 3e.)

(2) An amount that does not exceed 80 percent of the lowest maximum allowance for California established by the federal Medicare program for the same or similar item or service. (Refer to Reimbursement Methodology Table at page 3e.)

(b) Reimbursement for the rental or purchase of a wheelchair, wheelchair accessories, wheelchair replacement parts, and speech-generating devices and related accessories, with a specified maximum allowable rate established by Medicare shall be the lowest of the following:

(1) The amount billed in accordance with California Code of Regulations, Title 22, Section 51008.1 entitled “Upper Billing Limit”, that states that bills submitted shall not exceed an amount that is the lesser of the usual charges made to the general public, or the net purchase price of the item (as documented in the provider’s books and records),
schedule and any annual or periodic adjustments to the fee schedule are published in the provider manual and on the California Department of Health Services Medi-Cal website.

3. Reimbursement rates for orthotic and prosthetic appliances as described in State Plan Attachment 3.1-A, paragraph 12c, entitled “Prosthetic and Orthotic Appliances,” shall not exceed 80 percent of the lowest maximum allowance for California established by the federal Medicare program for the same or similar item. (Refer to Reimbursement Methodology Table at page 3f.)

4. Reimbursement rates for clinical laboratory or laboratory services as described in State Plan Attachment 3.1-A, paragraph 3, entitled “Laboratory, Radiological, and Radioisotope Services,” shall not exceed 80 percent of the lowest maximum allowance for California established by the federal Medicare program for the same or similar service. (Refer to Reimbursement Methodology Table at page 3f.)

5. Reimbursement rates for radiology services as described in State Plan Attachment 3.1-A, paragraph 3, entitled “Laboratory, Radiological, and Radioisotope Services,” shall not exceed 80 percent of the lowest maximum allowance for California established by the current federal Medicare program for the same or similar service. (Refer to Reimbursement Methodology Table at page 3f.)

6. Reimbursement rates for hearing aid services as described in State Plan Attachment 3.1-A, number 12c., titled “Prosthetics, durable medical equipment, and hearing aids,” shall not exceed the lesser of the following:

   (a) For hearing aids, including molds and inserts:

   (1) The maximum allowable amount established by the Department.
   (2) The one-unit wholesale cost, plus a markup determined by the Department.
   (3) The billed amount.
   (4) The rate established by the contracting program.
   (Refer to Reimbursement Methodology Table at page 3g.)

   (b) For hearing aid supplies and accessories:

   (1) The retail price.
   (2) The wholesale cost, plus a markup determined by the department.
   (3) The billed amount.
   (4) The rate established by the department's contracting program.

   (Refer to Reimbursement Methodology Table at page 3g.)
7. Reimbursement for enteral formulae, as described in State Plan Limitations on Attachment 3.1-A and 3.1-B, number 7c.4, shall be based on the estimated acquisition cost for that product plus a percentage markup determined by the Department. (Refer to Reimbursement Methodology Table at page 3g.)
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REIMBURSEMENT METHODOLOGY FOR ESTABLISHING REIMBURSEMENT RATES FOR DURABLE MEDICAL EQUIPMENT, ORTHOTIC AND PROSTHETIC APPLIANCES, LABORATORY, RADIOLOGY SERVICES, HEARING AID SERVICES, AND ENTERAL FORMULAE

1. The methodology utilized by the State Agency in establishing reimbursement rates for durable medical equipment as described in State Plan Attachment 3.1-A, paragraph 2a, entitled “Hospital Outpatient Department Services and Organized Outpatient Clinic Services”, and Paragraph 7c.2, entitled “Home Health Services Durable Medical Equipment”, will be as follows:

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   (b) Reimbursement for the rental or purchase of a wheelchair, wheelchair accessories, wheelchair replacement parts, and speech-generating devices and related accessories, with a specified maximum allowable rate established by Medicare shall be the lowest of the following:

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      (1) The maximum allowable amount established by the Department.
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AMOUNT, DURATION AND SCOPE OF SERVICES
PROVIDED TO MEDICALLY NEEDY GROUP(S) _________________

8. Private duty nursing services.
   - Provided: [ ] No limitations [ ] With limitations*

9. Clinic services.
   - Provided: [ ] No limitations [ ] With limitations*

10. Dental Services.
    - Provided: [ ] No limitations [ ] With limitations*

11. Physical therapy and related services.
    a. Physical therapy.
       - Provided: [ ] No limitations [ ] With limitations*
    b. Occupational therapy.
       - Provided: [ ] No limitations [ ] With limitations*
    c. Services for individuals with speech, hearing and language disorders provided by or under supervision of a speech pathologists or audiologist.
       - Provided: [ ] No limitations [ ] With limitations*

12. Prescribed drugs, dentures, prosthetic devices, durable medical equipment, and hearing aids; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.
    a. Prescribed drugs.
       - Provided: [ ] No limitations [ ] With limitations*
    b. Dentures.
       - Provided: [ ] No limitations [ ] With limitations*

*Description provided on attachment
c. Prosthetic devices, **durable medical equipment**, and hearing aids.

   - [X] Provided:   [ ] No limitations   [X] With limitations*

   - [ ] Provided:   [ ] No limitations   [ ] With limitations*

   d. Eye glasses.

   - [X] Provided:   [ ] No limitations   [X] With limitations*

   - [ ] Provided:   [ ] No limitations   [ ] With limitations*

13. Other diagnostic, screening, preventive, and rehabilitative services, i.e., other than those provided elsewhere in the plan.

   a. Diagnostic services.

   - [ ] Provided:   [ ] No limitations   [ ] With limitations*

   b. Screening services.

   - [ ] Provided:   [ ] No limitations   [ ] With limitations*

   c. Preventive services.

   - [ ] Provided:   [ ] No limitations   [ ] With limitations*

   d. Rehabilitative services; including rehabilitative mental health services and rehabilitative alcohol and drug treatment services for individuals diagnosed by physicians as having a substance-related disorder. (See Supplements 1, 2, and 3 to Attachment 3.1-B):

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14. Services for individuals age 65 or older in institutions for mental diseases.

   a. Inpatient hospital services.

   - [X] Provided:   [ ] No limitations   [X] With limitations*

   b. Skilled nursing facility services.

   - [X] Provided:   [ ] No limitations   [X] With limitations*

*Description provided on attachment*
State/Territory: California

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State/Territory: California

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED TO MEDICALLY NEEDY GROUP(S) _________________

c. Prosthetic devices, durable medical equipment, and hearing aids.

X Provided: No limitations X With limitations*

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