State of California—Health and Human Services Agency
Department of Health Care Services

TOBY DOUGLAS
DIRECTOR

EDMUND G. BROWN JR.
GOVERNOR

Ms. Gloria Nagle, Ph.D., MPA
Associate Regional Administrator
Centers for Medicare and Medicaid Services
Division of Medicaid and Children's Health
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION FOR STATE PLAN AMENDMENT 11-030

Dear Ms. Nagle:

The Department of Health Care Services (DHCS) is submitting this response to the Request for Additional Information (RAI) for State Plan Amendment (SPA) 11-030. DHCS originally responded to the February 29, 2012, questions regarding SPA 11-030 to the Centers for Medicare and Medicaid Services (CMS) on June 28, 2013. CMS had additional questions and concerns that were sent to DHCS on July 26, 2013, and DHCS submitted additional RAI responses on September 6, 2013. On September 12, 2013, DHCS sent a request to withdraw responses to the RAI and to stop the clock to allow more time to develop a revised mark-up and to preserve the November 1, 2011 effective date.

DHCS has been working with CMS informally, off the clock, to draft responses to the remaining RAI concerns applicable to SPA 11-030 (Enclosure 1). Specifically, the SPA language has been amended to describe the Reimbursement Methodology in more detail (Enclosures 2 & 3). The HCFA 179 form (Enclosure 4) has been previously submitted and has been revised; SPA 11-030 has no fiscal impact on the federal budget.

If you have any questions regarding the information provided, please contact Connie Florez, Chief, Provider Rates Section, at (916) 552-9589 or by e-mail at connie.florez@dhcs.ca.gov.

ORIGINAL SIGNED BY

TOBY DOUGLAS

Director

cc: Tom Schenck
Division of Medicaid & Children's Health Operations
San Francisco Regional Office
Centers for Medicare and Medicaid Services
90 Seventh Street, San Francisco, CA 94103

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: **11-030**

2. STATE: California

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
November 1, 2011

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

7. FEDERAL BUDGET IMPACT:
a. FFY 2012-13 **$0**
b. FFY 2013-14 **$0**

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 4.19-B, pages 3i, 3i.1, 3i.2, and 3j
Limitations on Attachment 3.1-A, page 14
Limitations on Attachment 3.1-B, page 14

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:

Limitations on Attachment 3.1-A, page 14
Limitations on Attachment 3.1-B, page 14

10. SUBJECT OF AMENDMENT:

Reimbursement methodology for hearing aids, durable medical equipment and enteral formulae.

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.

ORIGINAL SIGNED BY TOBY DOUGLAS

14. TITLE:
Director

15. DATE SUBMITTED: 6/17/14

16. RETURN TO:

Department of Health Care Services
Attn: State Plan Coordinator
1501 Capitol Avenue, Suite 71.3.26
P.O. Box 997417
Sacramento, CA 95899-7417

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

18. DATE APPROVED:

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

22. TITLE:

23. REMARKS:

FORM HCFA-179 (07-92)

CMS Request for Additional Information SPA 11-030
Sent February 29, 2012
State's response dated April 11, 2014

General Questions

1. Please redact from your submission and confirm pen and ink change to remove from the HCFA 179 the following pages:
    a. 3.1-A, page 5,
    b. Limitations on Attachments 3.1-A pages 18 and 18.a,
    c. 3.1-B pages 4 and 5, and
    d. Limitations on Attachments 3.1-B pages 18 and 18.a.

    State's response: The State is removing from our submission the above listed pages and confirms the pen and ink changes to remove the listed pages from the HCFA 179. In addition, the State requests a pen and ink change to remove Attachment 4.19-B, pages 3a, 3d, 3d.1 and 3g from the HCFA 179. We are replacing these pages with Attachment 4.19-B, pages 3i, 3i.1, and 3j.

2. According to the correspondence in the file, the State is amending the prosthetics' section of the State Plan at item 12c in order to clarify that DME is also available to beneficiaries who are not receiving home health services and to be clear that the State provides these services outside of home health services. For the reasons that follow, an amendment to add that clarification to the prosthetics' section at item 12c is not appropriate.
    a. Under regulations at 42 CFR 440.70, medical supplies, equipment, and appliances is a mandatory portion of the home health services benefit. Medical supplies, equipment and appliances are not limited to only people who are enrolled in a home health agency but also extend to beneficiaries who are not receiving home health services.

    b. People who need medical supplies, equipment and appliances must have the need reviewed by a physician annually.

    State's response: The State acknowledges it does not need to amend item 12c and is withdrawing pages 18 and 18a.

Reimbursement Questions:

1. Please confirm whether payment methodologies described in the proposed 4.19-B page 3d, 3d.1 and 3g reflect current payment methods for hearing aids, hearing aid supplies and accessories and enteral formulae. Please note that if the proposed payment methodologies described in 4.19-B results in any significant change in current payment methods and standards, public notice will be required according to 42 CFR 447.205.

State's response: The State confirms that the payment methodologies in the proposed Attachment 4.19-B, pages 3i, 3i.1, 3i.2 and 3j for these items reflect current payment methods.

2. Attachment 4.19-B, page 3d, item 6 (a), (b). Please explain the process of rate established by contracting program for hearing aids and hearing aid supplies and accessories. Also, please explain the difference between item 6(a) "The rate established by the contracting program" and 6(b) "The rate established by the department's contracting program."

   State's response (5/29/13): The State does not have a contracting program for hearing aids at this time. In 2008, the State released a Request for Proposal for contracting of hearing aids, but did not receive any bids. However, the State is retaining the contracting program language in the State Plan for possible future implementation. Both items 6(a) and (b) should state, "The rate established by the Department's contracting program," as referenced in Attachment 4.19-B, page 3i.

   CMS Comments (7/26/13): The State indicated in its response that the State currently does not have a contracting program for hearing aids. As such, please remove this payment option for hearing aids (a)(4), supplies and accessories (b)(4), mold or inserts (c)(3) and repairs (d)(3).

   State's response (4/21/14): The State agrees with CMS' suggestion to delete the references to a contracting program and has removed the language from Attachment 4.19-B page 3i (1) (a) (4), (b) (4), (c) (3) and page 3i.1 (d) (3).

3. Attachment 4.19-B, page 3d, item 6 (a), (b) and item 7. Please explain how the department determines the markup for hearing aids, hearing aids supplies and accessories, and enteral formulae.

   State's response (5/29/13): The State developed a reimbursement methodology for hearing aids at the beginning of coverage in 1974. Hearing aid maximum allowances are for new instruments plus a markup, which includes up to six post-sale visits for training, adjustments and fitting, an initial standard package of batteries, a cord, receiver, and such other components normally required for the use of the new instrument. The State determines a markup that generally reflects the reasonable cost of the related services.

   CMS Comments (7/26/13): Please explain how the State determines the "reasonable cost" for the markup. Please provide some examples of the markups on hearing aids, supplies and accessories.

   State's response (4/21/14): The industry standard that supports the reasonable cost for California's hearing aid mark-up is specified in the California Code of Regulations, title 22, section 51517, Payments for Services and Supplies, Hearing

Aids. Section 51517 states, “Reimbursement for hearing aids, hearing aid supplies and accessories, molds or inserts and repairs using the list of Healthcare Common Procedure Coding System codes billable to the Medi-Cal program, shall be the usual charges made to the general public not to exceed the maximum reimbursement rates published in the Medi-Cal Provider Manual, pursuant to Welfare and Institutions Code Section 14105.49.” Because California’s maximum reimbursement rates for hearing aids does not exceed the provider’s usual charges made to the general public, which is specified on the Medi-Cal claim form, the Department uses this information as a gage to ensure providers are reimbursed appropriately.

4. Attachment 4.19-B, page 3d, item 7. Please explain how the department determines the estimated acquisition cost for enteral formulae.

   State’s response (5/29/13): The State enters into contracts with manufacturers of enteral nutrition products for a maximum acquisition cost (MAC). The estimated acquisition cost (EAC) is based on the contracted MAC. On non-contracted products that are covered, the EAC is the average wholesale price minus 10 percent.

   CMS Comments 7/26/13: Please explain how the State determines the percentage of markup for the enteral formulae as described in proposed Attachment 4.19-B, page 3i (1)?

   State’s Response (4/21/2013): Pursuant to W&I Code section 14105.85, payment for enteral nutrition products dispensed by a pharmacy provider is based on the estimated acquisition cost for that product plus a percentage markup to be determined by the State in consultation with provider representatives from the California Association of Medical Product Suppliers and the California Pharmacists Association. The State, after the consultation with the provider representatives, established the same markup for enteral nutrition products as medical supplies dispensed by pharmacy providers.

   Pursuant to W&I Code section 14105.2, the allowable markup payable to dealers and pharmacies for dispensing medical supplies does not exceed 23 percent of the estimated acquisition cost of the item dispensed.

5. Attachment 4.19-B, page 3d, Item (6)(a)(1), please clarify whether “the maximum allowable amount established by the Department” refers to a fixed rate that providers would receive or does it refer to a range of the rates that providers can be paid up to the ceiling of the maximum rate?

   State’s response (5/29/13): The maximum allowable established by the State refers to a fixed rate.

CMS comments (7/26/13): Please explain what basis did the State use in developing the fixed rate for the maximum allowable amount (e.g., historical or average wholesale prices) as described in Attachment 4.19-B, page 3i (1)(a)(1) and (1)(c)(1).

State's response (4/21/14): The State developed the fixed rate for the maximum allowable based on the historical prices.

6. The following Standard Funding Questions are being asked and should be answered in relation to FQHCs PPS payment made to all providers reimbursed pursuant to a methodology described in Attachment 4.19-B of this SPA.

   a. Section 1903(a)(1) provides that Federal matching funds are only available for expenditures made by States for services under the approved State plan. Do providers receive and retain the total Medicaid expenditures claimed by the State (includes normal per diem, supplemental, enhanced payments, other) or is any portion of the payments returned to the State, local governmental entity, or any other intermediary organization? If providers are required to return any portion of payments, please provide a full description of the repayment process. Include in your response a full description of the methodology for the return of any of the payments, a complete listing of providers that return a portion of their payments, the amount or percentage of payments that are returned and the disposition and use of the funds once they are returned to the State (i.e., general fund, medical services account, etc.)

      State's response: SPA 11-030 does not apply to "FQHCs PPS payments;" therefore, this question is not applicable to this SPA transmission.

   b. Section 1902(a)(2) provides that the lack of adequate funds from local sources will not result in lowering the amount, duration, scope, or quality of care and services available under the plan. Please describe how the state share of each type of Medicaid payment (normal per diem, supplemental, enhanced, other) is funded. Please describe whether the state share is from appropriations from the legislature to the Medicaid agency, through intergovernmental transfer agreements (IGTs), certified public expenditures (CPEs), provider taxes, or any other mechanism used by the state to provide state share. Note that, if the appropriation is not to the Medicaid agency, the source of the state share would necessarily be derived through either through an IGT or CPE. In this case, please identify the agency to which the funds are appropriated. Please provide an estimate of total expenditure and State share amounts for each type of Medicaid payment. If any of the non-federal share is being provided using IGTs or CPEs, please fully describe the matching arrangement including when the state agency receives the transferred amounts from the local governmental entity transferring the funds. If CPEs are used, please

describe the methodology used by the state to verify that the total expenditures being certified are eligible for Federal matching funds in accordance with 42 CFR 433.51(b). For any payment funded by CPEs or IGTs, please provide the following: (i) a complete list of the names of entities transferring or certifying funds; (ii) the operational nature of the entity (state, county, city, other); (iii) the total amounts transferred or certified by each entity; (iv) clarify whether the certifying or transferring entity has general taxing authority: and, (v) whether the certifying or transferring entity received appropriations (identify level of appropriations).

State's response: Please refer to our response for Standard Funding Question in 6.a.

c. Section 1902(a)(30) requires that payments for services be consistent with efficiency, economy, and quality of care. Section 1903(a)(1) provides for Federal financial participation to States for expenditures for services under an approved State plan. If supplemental or enhanced payments are made, please provide the total amount for each type of supplemental or enhanced payment made to each provider type.

State's response: Please refer to our response for Standard Funding Question in 6.a.

d. For clinic or outpatient hospital services please provide a detailed description of the methodology used by the state to estimate the upper payment limit (UPL) for each class of providers (State owned or operated, non-state government owned or operated, and privately owned or operated). Please provide a current (i.e., applicable to the current rate year) UPL demonstration.

State's response: Please refer to our response for Standard Funding Question in 6.a.

e. Does any governmental provider receive payments that in the aggregate (normal per diem, supplemental, enhanced, other) exceed their reasonable costs of providing services? If payments exceed the cost of services, do you recoup the excess and return the Federal share of the excess to CMS on the quarterly expenditure report?

State's response: Please refer to our response for Standard Funding Question in 6.a.

Coverage Questions:

Only prosthetic devices are covered under item 12c. This benefit category could encompass certain DME devices such as hearing aids that would meet the definition at 42 CFR 440.120(c) but would not include non-prosthetic DME devices such as oxygen tanks or enteral formula which are covered under the home health benefit for all Medicaid eligibles as explained above. Therefore, in view of the fact that these services 1) are covered under the home health benefit and 2) non-prosthetic services are not covered in 12c, the State should withdraw the following pages: Att: 3.1-A/B page 5 (preprint pages cannot be revised to re-define the 12c benefit description), and Att. 3.1-A/B page 18 and 18a.

State's response: The State is withdrawing pages Attachment 3.1-A page 5, Attachment 3.1-B pages 4 and 5, and Limitations on Attachment 3.1-A/3/.1-B, pages 18 and 18a.

New Questions (informal): (7/26/2013)

1. Attachment 4.19-B, page 3i: The proposed reimbursement language for hearing aids, supplies/accessories, molds or inserts, and repairs is not clear to us. We suggest that the State revise the reimbursement language as follows:

   For (a), "The maximum reimbursement rate for hearing aids shall be the lowest of the following:"

   For (b), "The maximum reimbursement rate for hearing aid supplies and accessories shall be the lowest of the following:"

   For (c), - "The maximum reimbursement rate for molds or inserts shall be the lower of the following:"

   For (d), - "The maximum reimbursement for repairs, subsequent to the guarantee period, shall be the lower of the following:"

   State's Response (4/21/14): CMS retracted their suggested revision language from 7/26/13. SPA language amended in response to CMS new questions #2 in 3/11/14 informal question.

2. Please clarify whether the effective date language in Attachment 4.19-B, page 3i-1, section (3) refers back to either sections (1) or (2) or both (1) and (2).

State's Response (4/21/14) : The effective date language in Attachment 4.19-B, page 3i-1, section (3) applies to both (1) and (2).

New questions (informal): (3/11/14)

1. Since there is no current existing "contracting program" from which to give us a specific rate, any reference to the contracting programs for hearing aids should be removed.

   State's Response (4/8/14): This is addressed in the State's response to CMS on 3/4/14 on the first page, question #2. We added a 9/6/13 date to the response and believe this caused CMS to overlook the response. The date is revised to 3/14/2014.

   CMS Comments (4/8/14): CMS is still not comfortable with a non-existent contracting program being referenced as a reimbursement methodology in the State Plan. We are asking that this language be removed. A separate SPA can be submitted in the event a contracting program is developed.

   State's Response (4/8/14): The state is removing all language inreference to a contracting program.

2. Please see the redline changes that remove the word "maximum" from the primary sentences in (1)(a), (b), (c) 7 (d)

   State's Response (4/8/14): This is addressed in our 3/4/14 response as well on the second page, "New Questions" #1. The State's response is on page #3. The State agrees to amend Attachment 4.19-B, page 3i.

3. Please see the redline language that reflects the specific page numbers, rather than referencing 'this segment of the State Plan.'

   State's Response (4/8/14): The State received the redline language in Attachment 4.19-B, page 3i and agrees to the amended language.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: California

REIMBURSEMENT METHODOLOGY FOR HEARING AID SERVICES

(1) Definitions:

(a) Billed Amount: Includes actual product cost and related provider costs that include, but are not limited to, shipping, handling storage, and delivery.

(b) Retail Price: The usual and customary price charged to consumers for a particular product or service.

(c) Wholesale Cost: The unit price, or "the single unit" price as identified in the manufacturer's wholesale catalog, not including taxes, rebates and discounts.

(2) Reimbursement for hearing aid services as specified in the State Plan, Attachment 3.1-A entitled, "Amount, Duration, and Scope of Medical and Remedial Care and Services Provided to the Categorically Needy" and in Attachment 3.1-B entitled, "Amount, Duration and Scope of Services Provided to Medically Needy Groups," item 12c., entitled, "Prosthetic devices and hearing aids," will be subject to the following limitations:

(a) The reimbursement rate for hearing aids shall be the lowest of the following:

(1) The maximum allowable amount established by the Department of Health Care Services (Department).
(2) The one-unit wholesale cost, plus a markup determined by the Department.
(3) The billed amount.

(b) The reimbursement rate for hearing aid supplies and accessories shall be the lowest of the following:

(1) The retail price.
(2) The wholesale cost, plus a markup determined by the Department.
(3) The billed amount.

(c) The reimbursement rate for molds or inserts shall be the lower of the following:

(1) The maximum amount allowable established by the Department.
(2) The billed amount.

(d) The reimbursement for repairs, subsequent to the guarantee period, shall be the lower of the following:

(1) The invoice cost plus a markup determined by the Department.
(2) The billed amount.

(3) Hearing aid services, as specified in the State Plan, Attachment 3.1-A entitled, "Amount, Duration, and Scope of Medical and Remedial Care and Services Provided to the Categorically Needy" and Attachment 3.1-B entitled, "Amount, Duration and Scope of Services Provided to Medically Needy Groups," item 12c., entitled "Prosthetic devices and hearing aids," are subject to a "benefit cap amount" of $1,510. The "benefit cap amount" is the maximum amount of Medi-Cal coverage for hearing aid services for each beneficiary, for each fiscal year, as specified in California Welfare and Institutions Code section 14131.05 (as in effect on November 1, 2011).

Among the exceptions set forth in California law, the hearing aid "benefit cap amount" does not apply to the following:

(a) Replacement of hearing aids that are lost, stolen, or irreparably damaged due to circumstances beyond the beneficiary's control.
(b) Pregnancy-related benefits and benefits for the treatment of other conditions that might complicate the pregnancy.
(c) Beneficiaries under the Early and Periodic Screening, Diagnosis, and Treatment Program.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: California

(4) The State Agency's rates for the services, as discussed on pages 3i and 3i.1, were posted as of May 15, 2013, and are effective for dates of service on or after that date. The rates for these services are posted on the Medi-Cal Rates website at: http://files.medi-cal.ca.gov/pubsdoco/rates/rateshome.asp

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: California

REIMBURSEMENT METHODOLOGY FOR ENTERAL FORMULAE

(1) Reimbursement for enteral formulae, in accordance with California Welfare and Institutions Code section 14105.85, and as described in the State Plan Limitations in Attachment 3.1-A entitled, "Amount, Duration, and Scope of Medical and Remedial Care and Services Provided to the Categorically Needy," and Attachment 3.1-B entitled, "Amount, Duration and Scope of Services Provided to Medically Needy Groups," will be based on the estimated acquisition cost for that product plus a percentage markup determined by the department.

(2) The State Agency's rates for the services listed in this section were posted as of May 15, 2013, and are effective for dates of service on or after that date. The rates for these services are posted on the Medi-Cal Rates website at: http://files.medi-cal.ca.gov/pubsdoco/rates/rateshome.asp.

	TYPE OF SERVICE	PROGRAM COVERAGE**	PRIOR AUTHORIZATION OR OTHER REQUIREMENTS
7c.2	Durable medical equipment	Covered when prescribed by a licensed physician and reviewed annually. DME commonly used in providing SNF and ICF level of care is not separately billable. Common household items are not covered.	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.
7c.3	Hearing aids	Refer to Type of Service “12c Prosthetic and orthotic appliances, and hearing aids.”	Refer to Type of Service “12c Prosthetic and orthotic appliances, and hearing aids.”
7c.4	Enteral Formulae	Covered only when supplied by a pharmacy provider upon the prescription of a licensed physician 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.	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.

* Prior authorization is not required for emergency services.
** Coverage is limited to medically necessary services

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