



JENNIFER KENT
Director

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



EDMUND G. BROWN JR.
Governor

**NOTICE OF ADDITIONAL CHANGES TO THE TEXT OF PROPOSED
REGULATIONS AND ADDITION OF DOCUMENTATION TO THE RULEMAKING
FILE REGARDING**

**Authorization of Orthotic and Prosthetic Appliances & Services
(Title 22) DHCS-08-003**

Pursuant to Government Code Section 11346.8, notice is hereby given that the Department of Health Care Services (Department) is making additional changes to the text of the proposed subject regulations. A copy of the regulation text with the additional changes clearly indicated is attached.

Pursuant to Government Code Section 11347.1, notice is hereby given that the Department is adding supporting documentation to the rulemaking file for the proposed subject regulations.

The Department is making the additional proposed changes and the added documentation available for review during a 15-day public comment period.

WRITTEN COMMENT PERIOD

Any interested person or his or her duly authorized representative may submit written comments to the Department. *Only the additional changes to the proposed regulation text and supporting documentation added to the rulemaking file, as described in this notice, are subject to comment.*

Please label any comments as pertaining to Authorization of Orthotic and Prosthetic Appliances & Services – DHCS-08-003, and submit using any of the following methods:

Mail Delivery: Department of Health Care Services
Office of Regulations, MS 0015
P.O. Box 997413
Sacramento, CA 95899-7413

Hand Delivery: Department of Health Care Services
Office of Regulations
1501 Capitol Avenue, Suite 5084
Sacramento, CA 95814

FAX: (916) 440-5748

Email: regulations@dhcs.ca.gov

The Department will accept written comments from **April 23, 2015** through **May 7, 2015**. Any written comments, regardless of the method of transmittal must be received by the Office of Regulations by **5:00 p.m., on May 7, 2015**, for consideration and response by the Department in the Final Statement of Reasons.

Written comments should include the author's contact information so the Department can provide notification of any further changes to the regulation proposal.

METHOD OF INDICATING CHANGES

The additional changes to the text of the proposed regulations for Authorization of Orthotic and Prosthetic Appliances & Services – DHCS-08-003 are shown by using double strikethrough for deletions (~~double strikethrough for deletions~~) and double underline for additions (double underline for additions.)

SUMMARY OF ADDITIONAL PROPOSED CHANGES

Proposed changes to the regulation text, as a result of public comment, are as follows:

Section 51161:

1. Subsection (i) is amended, partially in response to comment, by deleting the word “and” and replacing it with “or” to provide clarity and flexibility for the authorization and reimbursement of this appliance.
2. Subsection (w) is amended by adding the phrase “positive or” to provide thoroughness in the definition of this appliance.
3. Subsection (z) is amended by adding the phrase “positive or” to provide thoroughness in the definition of this appliance and to be consistent with the change made to subsection (w).
4. Subsection (oo) is amended by adding the phrase “or lower” and deleting the word “upper” to provide thoroughness in the definition of this appliance.
5. Subsection (rr) is amended by correcting the spelling of the word “Hallus” to “Hallux.”
6. Subsection (zz) is amended by adding the phrase “or very soon” to provide thoroughness in the definition of this appliance.
7. Subsection (ddd) is amended by adding the phrase “and the capacity for normal activity, including employment” to be consistent with Welfare and Institutions (W&I) Code, Section 14059 and 42, Code of Federal Regulations, Section 438.210(a)(4)(ii)(B) and (C).

8. Subsection (kkk) is amended to delete the phrase “in a” and replace it with the phrases “who requires support attached to a” and “, chair or table” to provide thoroughness in the definition of this appliance and to provide for flexibility in the authorization and reimbursement of this appliance.
9. Subsection (ooo) is amended by correcting the spelling of the word “Hallus” to “Hallux” and to be consistent with the changes made to subsection (rr).
10. Subsection (uuu) is amended by adding the phrase “with no specific patient in mind” to provide thoroughness in the definition of this appliance.
11. Subsection (aaaa) is amended by adding the phrase “or a cosmetic cover for a passive or functional hand prosthesis” to provide thoroughness in the definition of this appliance.
12. Subsection (bbbb) is amended by adding the phrase “during normal use and resistant to normal use forces” to provide thoroughness in the definition of this appliance.

Section 51315:

1. Subsection (a) is amended by adding the phrase “or to support a weakened or deformed body member” to be consistent with DMEPOS Quality Standards developed and maintained by the Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) (June 2014), page 18, as provided by the commenter defining an orthosis. Refer to link below to access this document:
http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DMEPOS_Qual_Stand_Booklet_ICN905709.pdf
2. Subsection (a)(1) is amended by deleting the phrase “licensed pharmacist or” and replacing it with the word “certified” to be consistent with W&I Code, Section 14105.21, which specifies the provider types that may furnish Orthotic and Prosthetic (O&P) appliances.

This subsection is also amended by adding the phrase “A certified orthotist, prosthetist and orthotist/prosthetist shall hold current certification from The American Board for Certification in Orthotics, Prosthetics and Pedorthics or the Board of Certification/Accreditation or their successor organizations” to provide clarity in the determination of “certified orthotist,” “certified prosthetist” and “certified orthotist/prosthetist.”

3. Subsection (a)(2) is amended by adding the phrase “or a licensed podiatrist” in the specification of the provider types that may prescribe stock orthopedic and stock conventional shoes. Podiatrists are included as a provider type that can prescribe O&P appliances in existing subsection (a). A licensed podiatrist was inadvertently omitted from proposed subsection (a)(2), which should have included a licensed podiatrist as a provider type that can prescribe stock orthopedic and stock conventional shoes.
4. Subsection (a)(3) is amended by deleting the phrases “pharmacists or” and “pharmacist or,” and deleting the word “licensed” and replacing it with the word “certified” to be consistent with W&I Code, Section 14105.21, which specifies the provider types that may furnish O&P appliances.

5. Subsection (b) is amended by adding the phrase “/medical professional records” to provide thoroughness in the description of “clinical notes.”
6. Subsection (c)(1) is amended by adding the phrase “to support a weakened or deformed body member” to be consistent with the changes made to subsection (a) and with DMEPOS Quality Standards developed and maintained by the Department of Health and Human Services, CMS (June 2014), as provided by the commenter defining an orthosis.
7. Subsection (d)(3) is amended by adding the word “sole” to provide clarity in preventing the authorization and reimbursement of O&P appliances or services beyond basic coverage.

Section 51315.1:

1. Section 51315.1, Introduction is amended by adding the following paragraph:

“For purposes of this section, medical conditions cited with each appliance/service or group of appliances/services shall not be construed to represent an exhaustive list of medical conditions appropriate to each appliance/service or group of appliances/services. Likewise, such medical conditions may not be appropriate for authorization of the requested appliance/service if medical necessity for the specific appliance/service is not documented.”

This amendment is necessary to emphasize that (1) the lists of medical conditions in Section 51315.1 that follow many of the orthotic appliances and services are not intended to be exhaustive, and (2) not all of the listed medical conditions will necessarily require the orthotic appliance or service; documented medical necessity is required to be submitted with the Treatment Authorization Request (TAR), specific to the patient and the appliance(s) or service(s) being requested.

2. Subsection (i)(1)(A)2. is amended by adding the phrase “or a similar deformity or disease” to provide thoroughness in the description of this appliance.
3. Subsection (j)(5)(A) is amended by deleting the word “and” and replacing it with the word “or” to provide clarity and flexibility in the authorization and reimbursement of this appliance.
4. Subsection (j)(9) is amended by adding the words “beginning” and “and up” to provide clarity and flexibility in the authorization and reimbursement of this appliance.
5. Subsection (j)(9)(C)7.d. is amended by adding a new numbered condition to read “Any related medical condition affecting the spine” to provide thoroughness in the list of applicable medical conditions that may be appropriate for authorization and reimbursement of this appliance.
6. Subsection (j)(9)(D)5. is amended by deleting the words “Good motivation with” to provide clarity in the authorization and reimbursement of this appliance.
7. Subsection (k)(1) is amended by correcting the spelling of “Hallus” to “Hallux” to be consistent with the changes made to Sections 51161(rr) and (ooo).

8. Subsection (m)(2) is amended partially in response to public comment by deleting the word “uses” and replacing it with the phrases “requires such support attached to” and “, chair or table” to provide thoroughness in the description of this appliance, to provide flexibility in the authorization and reimbursement of this appliance and to be consistent with the changes made to Section 51161(kkk).
9. Subsection (m)(3)(B) is amended by adding the phrase “or functional” to provide thoroughness in the description of this appliance.
10. Subsection (p) is amended by adding the phrase “or a similar deformity or disease” to provide thoroughness in the description of this appliance.

Section 51315.2:

1. Section 51315.2, Introduction is amended by adding the following paragraph:

“For purposes of this section, medical conditions cited with each appliance/service or group of appliances/services shall not be construed to represent an exhaustive list of medical conditions appropriate to each appliance/service or group of appliances/services. Likewise, such medical conditions may not be appropriate for authorization of the requested appliance/service if medical necessity for the specific appliance/service is not documented.”

This amendment is necessary to emphasize that (1) the lists of medical conditions in Section 51315.2 that follow many of the prosthetic appliances and services are not intended to be exhaustive, and (2) not all of the listed medical conditions will necessarily require the prosthetic appliance or service; documented medical necessity is required to be submitted with the TAR, specific to the patient and the appliance(s) or service(s) being requested.

DOCUMENTATION ADDED TO THE RULEMAKING FILE

Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) – *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards* (June 2014) – page 18

http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DMEPOS_Qual_Stand_Booklet_ICN905709.pdf

CONTACT PERSONS

Inquiries regarding the additional changes to the text of the proposed regulations described in this notice may be directed to: Janice Spitzer, Chief, Benefits Analysis Section, at (916) 552-9422.

All other inquiries concerning the regulatory action described in this notice may be directed to Lori Manieri, of the Office of Regulations, at (916) 650-6825, or to the designated backup contact person, Jordan Espey, at (916) 445-1514.

ASSISTIVE SERVICES

The Department can also provide assistive services such as the conversion of written materials into Braille, large print, audiocassette, or computer disk. To request these assistive services, please call (916) 440-7695 (or California Relay at 711 or 1-800-735-2929), email – regulations@dhcs.ca.gov, or write to the Office of Regulations at the address noted above.

AVAILABILITY OF MATERIAL REGARDING THE REGULATORY ACTION

Materials regarding the regulatory action described in this notice (including this public notice and the additional changes to the text of the proposed regulations) are posted to the Department's Internet site at:

<http://www.dhcs.ca.gov/formsandpubs/laws/regs/Pages/08-003.aspx>