FINAL STATEMENT OF REASONS

As authorized by Government Code Section 11346.9(d), the Department of Health Care Services (Department) incorporates by reference the Initial Statement of Reasons prepared for this rulemaking.

PUBLIC COMMENT PERIODS / PUBLIC HEARING

The regulation text was made available for public comment for at least 45 days, from August 29, 2014 through October 24, 2014; seven persons submitted comments.

A public hearing was held on October 23, 2014, at 10:00 a.m., at the Auditorium of the East End Complex, located at 1500 Capitol Avenue in Sacramento, California. Six persons commented during the public hearing and one comment letter was received.

A 15-Day Public Availability, making further changes to the text and adding supporting documentation to the rulemaking file, was made available from April 23, 2015 through May 7, 2015; one person submitted comments.

SUMMARY AND RESPONSE TO PUBLIC / ORAL COMMENTS - ADDENDUMS

Summaries and responses to comments received during the 45-Day and 15-Day Public Comment Periods and at the Public Hearing are set forth in Addendums and attached to the Final Statement of Reasons, as follows:

- ADDENDUM 1 – Summary and Response to 45-Day Written Comments
- ADDENDUM 2 – Summary and Response to Oral Testimony at Public Hearing
- ADDENDUM 3 – Summary and Response to 15-Day Written Comments

A “List of Commenters” is also attached to the Final Statement of Reasons as a reference to the Addendums.

AMENDMENTS TO THE INITIAL STATEMENT OF REASONS

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, in response to comment, by adding the phrase “positive or” to clarify that Computed Aided Design/Computer Aided Manufacture Models can utilize both positive and negative models in the image capturing process.

3. Subsection (z) is amended, in response to comment, by adding the phrase “positive or” to clarify that Custom Fabricated appliances can utilize both positive and negative impressions in the creation of patterns and molds and to be consistent with the change made to subsection (w) above.

4. Subsection (oo) is amended, in response to comment, by adding the phrase “or lower” and deleting the word “upper” prior to “extremity fracture” to clarify that the orthosis can also traverse to the lower extremity.

5. Subsection (rr) is amended, in response to comment, by correcting the spelling of the word “Hallus” to “Hallux.”

6. Subsection (zz) is amended, in response to comment, by adding the phrase “or very soon” to clarify that “early” post surgical differs from “immediate” in that the device may not be applied to the patient for some time after surgery.

7. Subsection (ddd) is amended, in response to comment, 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, in response to comment, to delete the phrase “in a” and replace it with the phrases “who requires support attached to a” and “, chair or table” to provide other options in which to attach these supportive devices 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, in response to comment, by adding the phrase “with no specific patient in mind” to specify that “prefabricated devices” are standard molds and patterns manufactured in quantity without consideration of a specific patient type.

11. Subsection (aaaa) is amended, in response to comment, by adding the phrase “or a cosmetic cover for a passive or functional hand prosthesis” to specify that this appliance is also referred to as a cosmetic cover.

12. Subsection (bbbb) is amended, in response to comment, by adding the phrase “during normal use and resistant to normal use forces” to specify that “rigidity” exists when appliances are being used properly and are resistant to normal forces incurred during use.

Section 51315:

1. Subsection (a) is amended, in response to comment, 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, in response to comment, by deleting the phrase “licensed pharmacist or” and adding the word “certified” in reference to pharmacies, consistent with W&I Code, Section 14105.21, which specifies that pharmacies must be certified to claim reimbursement for furnishing Orthotic and Prosthetic (O&P) appliances. “Pharmacists” has

been deleted since they are not considered providers when acting independently. Pharmacies are the recognized provider type under Medi-Cal.

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 a reference for verification of the appropriate certification of these providers.

3. Subsection (a)(2) is amended, in response to comment, by adding the phrase "or a licensed podiatrist," which was inadvertently omitted as a provider type 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).

4. Subsection (a)(3) is amended, in response to comment, 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. "Pharmacists" has been deleted since they are not considered providers when acting independently. Pharmacies are the recognized provider type under Medi-Cal.

5. Subsection (b) is amended, in response to comment, by adding the phrase "/medical professional records" to clarify that "clinical notes" refer to all medical professional records that serve to describe the patient and justify medical necessity for the requested appliance or service.

6. Subsection (c)(1) is amended, in response to comment, by adding the phrase "to support a weakened or deformed body member" to more closely match established definitions of orthoses and to be consistent with the changes made to subsection (a) and with *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards* developed and maintained by the Department of Health and Human Services, CMS (June 2014).

7. Subsection (d)(3) is amended, in response to comment, by adding the word "sole" to provide clarity and to prevent 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; and 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, in response to comment, by adding the phrase "or a similar deformity or disease" so as not to limit the authorization of this appliance for specific diseases or conditions.

3. Subsection (j)(5)(A) is amended, in response to comment, 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, in response to comment, by adding the words "beginning" and "and up" to provide clarity and flexibility – that the appliance shall be authorized when it is developmentally appropriate, starting at around the age of two and up.

5. Subsection (j)(9)(C)7.d. is amended, in response to comment, by adding "Any related medical condition affecting the spine" so as not to limit medical conditions that may be appropriate for authorization and reimbursement of this appliance.

6. Subsection (j)(9)(D)5. is amended, in response to comment, by deleting the words "Good motivation with" as this phrase is not relevant in the determination for authorization and reimbursement of this appliance. The lower case "r" for the term "realistic" is changed to an upper case "R" for purposes of grammar.

7. Subsection (k)(1) is amended, in response to comment, 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 options other than a wheelchair in which to attach these supportive devices, and to be consistent with the changes made to Section 51161(kkk).

9. Subsection (m)(3)(B) is amended in response to comment, by adding the phrase "or functional" to clarify that this appliance is used to support a patient's functional activities as well as medical needs.

10. Subsection (p) is amended, in response to comment, by adding the phrase "or a similar deformity or disease" so as to not limit the authorization of this appliance for specific diseases or conditions, and to be consistent with the changes made to Section 51315.1(i)(1)(A)2.

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; and documented medical necessity is required to be submitted with the TAR, specific to the patient and the appliance(s) or service(s) being requested.

MATERIALS RELIED UPON

Pursuant to Government Code Section 11347.1, the Department added supporting documentation to the rulemaking file for the proposed subject regulations, as follows:

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

Persons who commented during the public comment period and testified at the public hearing were notified of such added documentation during the 15-Day Public Availability.

LOCAL MANDATE DETERMINATION

The Department has determined that the proposed regulations would neither impose a new mandate on local agencies or school districts, nor any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

ALTERNATIVES CONSIDERED

The Department has determined that no reasonable alternative considered by the Department, or otherwise identified and brought to the attention of the Department, would be more effective in carrying out the purpose for which this regulatory action was taken, would be as effective and less burdensome to affected private persons than the regulatory action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The proposed regulations are the most effective way to identify medical necessity criteria and other requirements under which O&P appliances and services shall be authorized. The regulations are consistent with W&I Code Sections 14133.9 and 14133.3 regarding the development and publication of such medical criteria and provide convenient access to this information for providers of O&P appliances and services.