NOTICE OF PROPOSED RULEMAKING

SUBJECT: Authorization of Orthotic and Prosthetic Appliances and Services DHCS-08-003

NOTICE IS HEREBY GIVEN that the Department of Health Care Services (Department) proposes to adopt Sections 51315.1 and 51315.2 and amend Sections 51161 and 51315, Title 22, Division 3, Chapter 3, of the California Code of Regulations (CCR), after considering all public comments, objections, and recommendations.

WRITTEN COMMENT PERIOD

Any interested person or his or her duly authorized representative may submit written comments to the Department relevant to the regulatory action described in this notice.

Please label any comments as pertaining to Authorization of Orthotic and Prosthetic (O&P) Appliances and 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 written comment period closes at **5:00 p.m., on October 13, 2014;** any written comments regardless of the method of transmittal, must be received by the Office of Regulations by **5:00 p.m.** on this date for consideration.

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

A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a hearing if a written request for a public hearing is received from any interested person or his or her duly authorized representative, no later than 15 days prior to the close of the written comment period, pursuant to Government Code Section 11346.8.

The Department shall consider all comments received regarding the proposal equally, whether submitted in writing or through oral testimony at a public hearing.

AUTHORITY AND REFERENCE

These regulations are being proposed under the following authorities:

Section 20, Health and Safety Code; and Sections 10725, 14103.7, 14105 and 14124.5, Welfare and Institutions (W&I) Code.

These regulations implement, interpret, or make specific the following:

Sections 14103.7, 14105.21, 14131, 14132, 14133, 14133.1, 14133.3 and 14133.9, W&I Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Medi-Cal, California's Medicaid Program, is administered by the Department. Medi-Cal provides health care services for low income individuals, including children, families with children, seniors, persons with disabilities, children in foster care, and pregnant women.

W&I Code Sections 10725, 14103.7 and 14124.5, authorize the director of the Department to adopt, amend, or repeal regulations as necessary and proper to carry out the purpose and intent of the laws enforced by the Department. Specifically, under the W&I Code, Chapter 7, Basic Health Care, Section 14000 states that the purpose of this chapter is to afford qualifying individuals health care services. The uniform schedule of health care benefits under Medi-Cal are specifically described under Section 14131, et seq., and include O&P appliances and services, as specified under W&I Code Section 14132(k).

This regulatory proposal will amend and establish requirements (including medical necessity criteria) that are specific for the prior authorization and reimbursement of O&P appliances and services under Medi-Cal, which is consistent with W&I Code Section 14133.9, regarding the development and publication of such medical criteria. The establishment of these requirements is also consistent with W&I Code Section 14133.3, which specifies that providers shall offer fully documented medical justification demonstrating that the requested services are medically necessary.

Anticipated Benefits or Goals of the Regulations

Establishing and amending O&P requirements within the CCR, will benefit Medi-Cal providers who prescribe and those who furnish the O&P appliances and services, by clearly outlining the criteria that must be met in a prior authorization process. This in turn will facilitate access to and delivery of the O&P appliances and services to the beneficiaries. These requirements will also serve as a principal assessment tool for Department representatives during the prior authorization review process, which supports utilization control for Medi-Cal, as required and authorized by W&I Code Section 14133, et seq. and Title 42, United States Code Section 1396a(a)(30) (see also, CCR Sections 51003 and 51159).

As required by the authorizing statutes (as described above), these proposed regulations ensure the proper and efficient administration of the Medi-Cal program, and safeguard against unnecessary utilization, waste and fraud, in accordance with the federal and state laws that govern Medi-Cal. The proposed regulations also benefit the health and welfare of California residents by providing Medi-Cal beneficiaries the delivery of medically necessary O&P appliances and services.

Consistency and Compatibility with Existing State Regulations

The Department has conducted an evaluation of the related existing state regulations in CCR, Title 22, Division 3, and has determined the proposed regulations are consistent and compatible with those regulations.

Regulatory Sections

Specifically, this regulatory action:

1. Amends Section 51161, to define medical terms and phrases related to the prior authorization process of O&P appliances and services.
2. Amends Section 51315, to:
    - Specify the type of providers that may prescribe and those that may furnish O&P appliances and services.
    - Identify the circumstances under which O&P appliances and services shall and shall not be authorized.
    - Specify the requirements (medical necessity criteria) that shall be met for the prior authorization of O&P appliances and services.
    - Establish written prescription and electronic image/data transmission prescription requirements.
    - Indicate supporting medical documentation requirements (clinical notes) and the circumstances under which these requirements shall be met for prior authorization to be granted.
    - Clarify how cumulative costs for O&P appliances and services impact prior authorization.
    - Make non-substantive changes, including formatting, re-designations and punctuation.
3. Adopts Section 51315.1, to provide requirements (including medical necessity criteria) specific to the prior authorization of orthotic appliances and services.

4. Adopts Section 51315.2, to provide requirements (including medical necessity criteria) specific to the prior authorization of prosthetic appliances and services.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

Estimated Fiscal Impact Statement

A. Costs to any Local Agency or School District that is not reimbursable by the State: None.

Costs to any Local Agency or School District that is required to be reimbursed Under Part 7 (commencing with Section 17500), Division 4 of the Government Code: None.

B. Costs or Savings to any State Agency: None.

C. Costs or Savings in Federal Funding to the State: None.

D. Other Nondiscretionary Costs or Savings Including Revenue Changes Imposed on State or Local Governments: None.

All cost impacts, known to the Department at the time the notice of proposed action was submitted to the Office of Administrative Law, that a representative private person or business would necessarily incur in reasonable compliance with the proposed action:

The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Mandates on Local Agencies or School Districts

The Department has determined that the proposed regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

Significant Statewide Adverse Economic Impact Affecting Businesses

The Department has made an initial determination that the proposed regulations would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

Results of the Economic Impact Assessment (Analysis)

In accordance with Government Code Section 11346.3(b)(1), the Department has made the following assessments and has determined that the proposed regulations would not significantly affect the following:

(1) The creation or elimination of jobs in California.

(2) The creation or elimination of businesses in California.

(3) The expansion of businesses currently doing business in California.

Impact on Jobs and Businesses

The California's Medicaid program, Medi-Cal, continues to be a joint federal/state public health program that offers health care services for eligible low-income individuals who choose to enroll and participate in the program. This regulatory proposal establishes requirements (including medical necessity criteria) specific for the authorization and reimbursement of O&P appliances and services under Medi-Cal. These requirements serve as a principal assessment tool for Department representatives during the authorization process, which supports utilization control for Medi-Cal. This regulatory proposal will impact only those providers who choose to participate in Medi-Cal and who prescribe and furnish O&P appliances and services to Medi-Cal beneficiaries. The requirements (medical necessity criteria) and other requirements as proposed to be adopted and amended through these regulations are not anticipated to have an impact on the creation or elimination of jobs, the creation of new business, the elimination of existing business or the expansion of businesses in California.

Benefits of the Proposed Regulation

The Department has determined that the proposed regulations will not specifically affect worker safety or the state's environment. However, the proposed regulations will benefit the health and welfare of California residents by providing Medi-Cal beneficiaries the delivery of medically necessary O&P appliances and services. This regulatory proposal ensures the proper and efficient administration of Medi-Cal, in accordance with federal and state laws.

Effect on Small Businesses

The Department has determined that the proposed regulations would only affect small businesses that voluntarily participate in the Medi-Cal program and provide O&P appliances and services.

Housing Costs Determination

The Department has determined that the proposed regulations would have no effect on housing costs.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed 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 Department has determined that 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.

ASSISTIVE SERVICES

For individuals with disabilities, the Department can provide assistive services such as the conversion of written materials into Braille, large print, audiocassette and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takers, reading or writing assistance. 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. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

The Department shall provide, upon request from a person with a visual disability or other disability for which effective communication is required under state or federal law, a narrative description of the additions to, and deletions from, the California Code of Regulations or other publication in a manner that allows for accurate translation by reading software used by the visually impaired. Providing this description may require extending the period of public comment for the proposed action pursuant to Government Code Section 11346.6.

CONTACT PERSONS

Inquiries regarding the substance of the 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, Office of Regulations, at (916) 650-6825, or to the designated backup contact person, Lynette Cordell, at (916) 440-7695.

AVAILABILITY OF TEXT OF REGULATIONS AND STATEMENT OF REASONS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file). In addition, a copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

The full text of any regulation which is changed or modified from the express terms of this proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) are posted to the Department's Internet site at:
http://www.dhcs.ca.gov/formsandpubs/laws/Pages/ProposedRegulations.aspx.

In order to request a copy of this public notice, the regulation text, and the initial statement of reasons be mailed to you, 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.