INITIAL STATEMENT OF REASONS

Medi-Cal, California's Medicaid Program, is administered by the Department of Health Care Services (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.

Welfare and Institutions (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 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 W&I Code Section 14131, et seq., and include Orthotic and Prosthetic (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 requested services are medically necessary.

Establishing and amending O&P requirements within the California Code of Regulations (CCR), will benefit Medi-Cal providers who prescribe and those who furnish O&P appliances and services, by clearly outlining the criteria that must be met for prior authorization. This in turn facilitates access to and delivery of O&P appliances and services to 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.

Specifically, this regulatory action:

1. Amends Section 51161, to define medical terms and phrases related to the prior authorization process for O&P appliances and services.
2. Amends Section 51315 to:
    - Specify the type of providers who may prescribe and those who 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.

The specific purpose and rationale for each change to Title 22, CCR are identified below.

Section 51161, Orthotic and Prosthetic Appliances and Services.

Section 51161, is amended to:

1. [Title of section] Reverse the “prosthetic and orthotic appliances” terminology to read “orthotic and prosthetic appliances” to be consistent with the current industry terminology; and add the phrase “and services” to “orthotic and prosthetic appliances” to be more complete in the description of what is available under Medi-Cal.
2. [Introductory statement] Remove outdated language. Specific O&P definitions are adopted in this section, so the introductory statement is not needed.
3. [New introductory statement] Establish that the listed definitions in this section apply only to Sections 51315, 51315.1, and 51315.2, and are those terms and the meaning of those terms that pertain to the prior authorization of O&P appliances and services.
4. [Subsections (a) through (vvvv)] Specify definitions for words and phrases frequently used in regard to prior authorization for O&P appliances and services. The proposed definitions are alphabetized for ease in locating and to be consistent with typical CCR formatting.

The proposed definitions, with the exception of the subsections noted below, are derived in part from the Illustrated Guide to Orthotics and Prosthetics (2012) (IGOP), published by the American Orthotic and Prosthetic Association (AOPA).
The definitions are identical to those in the IGOP, except for non-substantive edits. This IGOP is used by the Department as a professional reference for prior authorization purposes and is considered the “authority” of the O&P industry. The

Department chose to include only those definitions from the IGOP directly related to the prior authorization of O&P appliances and services.

The definitions found in subsections (c), (e), (g), (h), (i), (n), (o), (u), (y), (z), (hh), (mm), (oo), (vv), (xx), (fff), (hhh), (iii), (mmm), (rrr) and (ttt) were developed by the Department through consultation with O&P experts, both within and outside of the Department, including AOPA staff and Department orthotists, prosthetists, and physicians. These definitions were drafted in a manner to be easily understood by those in the O&P field and to meet the current O&P standards of practice.

Specification of these definitions allows all parties involved in O&P prior authorization, including Department staff, providers, and other stakeholders to refer to these appliances and services through a common language.

Section 51315, Amount, Scope, Duration, Limitation and Prior Authorization of Benefits for Orthotic and Prosthetic Appliances and Services.

Section 51315, is amended to:

1. [Title of section and throughout the section] Reverse the “prosthetic and orthotic appliances” terminology to read “orthotic and prosthetic appliances” to be consistent with current industry terminology; and to add the phrase “and services” to “orthotic and prosthetic appliances” to be more complete in the description of what is available under Medi-Cal. The words “amount, scope, duration, limitation and prior authorization of benefits” are included in the title to further clarify the purpose of the section.
2. [Subsection (a)] Establish a lead in sentence for subsections (a)(1) through (3) that specifies what Medi-Cal covers in regard to O&P appliances and services including the provider types authorized to prescribe and furnish these appliances and services and the relevant exceptions. The majority of this language is existing under prior subsection (a).
3. [New subsection (a)(1)] Outline and provide convenient cross references to the exceptions of coverage for O&P appliances and services, specifically to subsection (a)(2) regarding shoes and to W&I Code Section 14131.10, which describes exclusions (and exemptions) regarding podiatric and adult dental services. Further, this subsection identifies providers who may prescribe O&P appliances and services, including the addition of a “licensed non-physician medical practitioner” (NMP), because NMPs may prescribe services under their scope of practice. The terms “licensed” and “certified” are added before each prescribing and/or furnishing provider to clarify that these providers must be licensed and/or certified to participate in Medi-Cal. The word “furnish” is used to clearly delineate the action from “prescribe.” The terms physician, dentist, and podiatrist are included to replace the more generic language of “licensed practitioner” for clarity. In addition, this subsection establishes that licensed pharmacists and pharmacies may furnish O&P appliances and services and includes a cross reference to subsection (a)(3) for convenience. Much of the language proposed under subsection (a) has been transferred from existing

subsection (e), including the provision that a pharmacist may furnish O&P appliances and services. The provisions from the last sentence under subsection (a)(1) are transferred to and elaborated upon under subsection (b).

4. [New subsection (a)(2)] Establish that only a licensed physician may prescribe stock orthopedic and stock conventional shoes and only a certified orthotist, certified prosthetist, or certified orthotist/prosthetist may furnish these shoes. This is necessary to ensure these specialty shoes are appropriately prescribed and furnished and to allow the Department to maintain utilization control over these appliances. A cross reference to Section 51315.1(k)(3) is also provided for convenience.
5. [New subsection (a)(3)] Include existing language from subsection (e) regarding pharmacists furnishing and billing for O&P appliances and services. Pharmacies are included along with pharmacists under this subsection, because they are also considered Medi-Cal providers. This subsection specifies that pharmacists and pharmacies must be licensed and enrolled in Medi-Cal to furnish and bill for O&P appliances, which is similar to the other providers described under subsection (a)(1).
6. [New subsection (b)] Include language similar to existing subsection (a) (as proposed to be deleted); separating provisions regarding coverage under subsection (a), from those pertaining to record keeping and prior authorization requests under subsection (b). In accordance with the record keeping requirements of Section 51476, as cross referenced here for convenience, the patient's medical record must include a signed written prescription and clinical notes from the provider(s). This will ensure the appliances or services are medically necessary, serving as a measure of utilization control for Medi-Cal. Subsection (b) also requires that a copy of the signed prescription or electronic image/data transmission prescription and medical necessity documentation accompany the prior authorization request. This is necessary to demonstrate the treating provider's request for the O&P appliance or service to meet the patient's specific medical need(s), which is consistent with W&I Code Section 14133.3, and supports utilization control under Medi-Cal. Electronic prescription transmission is included to accommodate the option of more recent technology, including the cross reference to Health and Safety Code Section 11027, which is provided for clarity and convenience. A cross reference to subsection (c), which outlines medical necessity documentation, is also included for clarity and convenience. The end of this subsection serves as a lead into paragraphs (1) and (2) which outline the circumstances under which a prior authorization request is required.
7. [Subsections (b)(1) and (2)] Remove the procedure codes, which is consistent with W&I Code Section 14105.21(e) that required the repeal of Title 22, CCR Section 51515, which included O&P appliance procedure codes and maximum allowances (this action was done through OAL File # 04-0312-01C). The term "beneficiary" is replaced with "patient" for consistent use of this term throughout the proposal. Under subsection (b)(1) and (2) various amendments are included that make the regulations consistent with established Medi-Cal billing procedures. These amendments establish the beginning of the 90-day period as

the date of service not the date of payment. The cumulative time clock for services rendered under Medi-Cal always begins on the date of service.

8. [Subsection (b)(3)] Remove the phrase “unlisted, By Report, and By Invoice,” and replace it with language that is more accurate and inclusive, which allows for other circumstances where a procedure code or rate may be absent, e.g., a situation where a provider bills for an appliance “by report” even if there is a procedure code on file for that appliance.
9. [Existing subsection (b), re-designated as subsection (c)] Re-designate existing subsection (c) due to the addition of new subsection (b).
10. [Re-designated subsection (c)] Clarify and make specific the medical documentation requirements and medical criteria that must be met in order for O&P appliances and services to be authorized. The amendments to this subsection are necessary to ensure providers demonstrate the patient’s specific medical needs along with the necessity for a particular O&P appliance or service. These amendments are consistent with W&I Code Section 14133.9(c) regarding the development and publication of such medical criteria and with W&I Code Section 14133.3, which supports utilization control under Medi-Cal by requiring supportive medical documentation for requested services. For clarity and convenience subsection (c) specifies the location of the medical criteria that must be met and clearly substantiated along with the prior authorization request.
11. [Subsection (c)(1)] Require that the requested appliance or service is medically necessary for the restoration of bodily functions or for the replacement of a body part and is reasonable and necessary to protect life, to prevent significant illness or disability, or to alleviate severe pain. Medical necessity is a standard of criteria for the provision of health care services under Medi-Cal and is consistent with W&I Code Sections 14059.5 and 14133.3.
12. [Subsection (c)(2)] Require that the requested appliance or service is essential to perform activities of daily living (ADLs) or instrumental activities of daily living (IADLs). This requirement further describes “reasonable and necessary” as specified in subsection (c)(1). The ability to perform ADLs and IADLs is a measure of necessity for the appliance or service.
13. [Subsection (c)(3)] Require that the requested appliance or service is consistent with the patient’s previous abilities and limitations, as they relate to ADLs or IADLs, prior to the onset of the disability or injury and that the appliance or service is appropriate for the patient’s chronological and developmental age. O&P appliances and services are intended to support medical necessity and maintain appropriate function, so they will not be authorized for the purpose of giving the patient physical ability that did not exist prior to the onset of a disability or injury, or that the patient would not otherwise have, based on chronological and developmental age. If the patient has a disability since birth or childhood, O&P appliances or services will support and focus on the performance of ADLs/IADLs expected at a patient’s current level of development and age.
14. [Subsection (c)(4)] Require that the requested appliance or service is consistent with the patient’s overall medical condition. This requirement is necessary to ensure an appliance or service is beneficial to and is consistent with the patient’s

current medical status, and to preclude prior authorization of an appliance or service that doesn't provide this aligned support.

15. [Subsection (c)(5)] Require that the requested appliance or service is the lowest cost option that meets the patient's medical need(s). This requirement is consistent with Section 51003(f) and precludes Medi-Cal from paying for an appliance or service that exceeds the patient's needs and is more costly. Note: The criteria specified in subsections (c)(1) through (5) are widely accepted by the industry and in the community as being reasonable benchmarks for prior authorization of O&P appliances and services. Specification of these criteria is necessary as part of the Department's utilization control efforts and to prevent requests, or prior authorization for, unnecessary appliances and services, while still allowing for appropriate access to O&P appliances and services for medically needy patients.
16. [New subsection (d)] Establish a lead-in sentence for paragraphs (1) through (7) that outline specific situations where O&P appliances and services will not be authorized. This is necessary to avoid the submission of provider prior authorization requests that will not be granted.
17. [Subsection (d)(1)] Preclude the prior authorization of O&P back-up appliances except under certain circumstances. The Department has chosen to exempt primary appliances that are worn 24 hours per day that must be cleaned on a regular basis, and cannot be dried overnight. Frequently, with regard to O&P appliances, a patient can wait for repair/replacement without risk or hardship.
18. [Subsection (d)(2)] Preclude the prior authorization of O&P appliances or services for the sole purpose of cosmetic restoration. Section 51003 provides that all services under Medi-Cal must be based upon the medical need(s) of the patient. No appliance or service (including non-O&P) is provided under Medi-Cal for the sole purpose of cosmetic restoration.
19. [Subsection (d)(3)] Preclude the prior authorization of O&P appliances or services for the purpose of restoring functions beyond ADLs or IADLs, such as athletic activities. This provision is the inverse of and consistent with the criteria established in subsections (c)(2) and (3). O&P appliances and services are authorized under Medi-Cal only to meet the medical needs and maintain functionality at the patient's expected level of development or age.
20. [Subsection (d)(4)] Preclude the prior authorization of O&P appliances or services that are benefits and are included as part of the acute inpatient hospital stay. If the O&P appliance or service is included in the hospital's contract with the Department as part of the hospital stay, reimbursement is provided as part of the contract. Payment outside of this established agreement would be duplicative and not allowable. The request for O&P appliances or services, which fall outside of the contract between the Department and an inpatient acute care hospital, shall be subject to the provisions under this regulatory action.
21. [Subsection (d)(5)] Preclude the prior authorization for repair of O&P appliances when the repair cost is equal to or greater than the cost of purchasing a new appliance. This restriction promotes cost effectiveness under Medi-Cal by prohibiting the unnecessary repair of appliances when it would be the same cost or less costly to purchase a new appliance.

22. [Subsection (d)(6)] Preclude the prior authorization for purchase of an O&P appliance when the patient's existing appliance can be repaired for less than the cost of replacement, unless the existing appliance does not meet the patient's medical need(s). This provision is the inverse of and consistent with the criteria established in subsection (d)(5). This restriction promotes cost effectiveness under Medi-Cal by prohibiting the unnecessary purchase of appliances when it would be less costly to repair the existing appliance. This subsection also specifies that provider documentation regarding medical necessity is required, if an existing appliance does not meet the patient's need(s), and a new appliance must be purchased to maintain functionality.
23. [Subsection (d)(7)] Preclude the prior authorization for fitting, measuring, training, or delivery of O&P appliances outside of the initial prior authorization for the appliance. These services are authorized and reimbursed only as part of the initial prior authorization, because payment outside of this process would be duplicative and not allowable.
    Note: The restrictions under subsections (d)(1) through (7) are widely accepted by the industry and in the community as being reasonable restrictions on the prior authorization of O&P appliances and services. Specification of these restrictions is necessary as part of the Department's utilization control efforts and to prevent prior authorization requests, or prior authorization for, unnecessary appliances and services, while still allowing for appropriate access to O&P appliances and services.
24. [Existing subsections (c), (d) and (e)] Repeal designated subsections and place language in appropriate new sections/subsections. The language from subsection (c) is included under new subsection (d)(5) and is specific to prior authorization; the language from subsection (d) is included under proposed Section 51315.1(k) and throughout other areas of the specified criteria; and the language from subsection (e) is included in amended and new subsections (a)(1) and (a)(3), excluding cross references determined to be superfluous.
25. [Existing subsection (f), redesignated as subsection (e)] Make the language consistent with the opening statement under subsection (a) and add "shall be subject to the following," to serve as a lead into the subsequent requirements. The phrase "or service(s)" is included under paragraphs (1) and (2) where it had been inadvertently excluded; the term "lesser" is replaced with "lowest" for clarity under paragraph (2); and the term "basic" is replaced with "base" for clarity under paragraph (3). Also, under paragraph (3), the terms "these" and "appliances" are changed to "the" and "appliance" (singular form). Subsection (f)(4) is also removed because the language is proposed under new subsection (d)(7). A new subsection (e)(4) is added to specify the requirements under Section 51315(c) must be met for reimbursement of O&P appliances and services, even when prior authorization is not required. W&I Code Section 14133.3, specifies that providers shall offer fully documented medical justification demonstrating requested services are medically necessary. This medical necessity standard applies for both services that require prior authorization, and those that do not.

Sections 51315.1 & 51315.2 – Requirements Applicable to the Prior Authorization of Orthotic and Prosthetic Appliances and Services.

Section 51315.1 (orthotics) and Section 51315.2 (prosthetics) are proposed to be adopted to provide detailed medical necessity criteria related to the prior authorization of these appliances and services. These sections support the criteria outlined in Section 51315, which pertain to both orthotics and prosthetics.

Pursuant to W&I Code Section 14105.21, a list of covered services and reimbursement rates for O&P appliances are maintained in a provider manual, while the specific medical criteria for these appliances and associated services are proposed to be included in Section 51315.1, for orthotics and 51315.2, for prosthetics.

The medical necessity criteria specified in Sections 51315.1 and 51315.2 meet current O&P standards of practice and are known to be widely accepted by professionals in the orthotic and prosthetic fields of medicine as being appropriate to each specific appliance or service. These criteria were developed in consultation with O&P experts, both within and outside of the Department, including AOPA staff and Department orthotists, prosthetists and physicians, who have knowledge and understanding of the specialty functions of O&P appliances and associated services.

In addition to the direct consultation from O&P experts as described above, the content of the proposed medical criteria under Sections 51315.1 and 51315.2, are in part from and are consistent with the Healthcare Common Procedure Coding System (2012 HCPCS Level II Professional Edition), published by the American Medical Association. The HCPCS manual is the Centers for Medicare & Medicaid Services' (CMS) official publication for coding under the Federal Medicare and Medicaid programs. This manual includes current O&P terms commonly understood and used interchangeably in the industry. This terminology is similarly reflected within Sections 51315.1 and 51315.2, e.g., the use of the terms "device," "appliance," and "procedure," all have the same commonly understood meaning. The medical criteria proposed in Sections 51315.1 and 51315.2 are also derived from the IGOP and described in detail under Section 51315 above.

In accordance with W&I Code Section 14133.9, establishment of these criteria are necessary to the professional judgment of Department representatives in their decisions as to whether a service is medically necessary. Instituting these criteria also offers consistent information for providers and other stakeholders regarding the requirements that must be met for the prior authorization of a requested O&P appliance or service. These criteria support cost effectiveness under Medi-Cal, through the prior authorization of O&P appliances and services that meet the patient's medical need(s) at a reasonable cost.

The criteria outlined in these two sections include some frequently used phrases understood by O&P providers participating in Medi-Cal. These phrases and meanings include:

- "Appropriate to the requested procedure code(s)" is understood to mean the target procedure code grouping has more than one treatment mode or purpose, depending upon the specific procedure code.
- "Existing or authorized appliance", e.g., existing or authorized compression stocking, is understood to mean the patient either has his or her own appliance that may have been authorized and/or reimbursed by Medi-Cal at an earlier time, may have been reimbursed by a third party, or the appliance is being authorized at the same time as the appliance(s) or service(s) being requested.
- "Related medical condition" is understood to mean a medical condition similar to those listed may also be appropriate for the prior authorization of the requested O&P appliance or service. The determination of "related" medical conditions is initially conducted by the patient's physician and/or orthotist/prosthetist, which is followed by a review of the initial prior authorization request (or claim if the appliance or service does not require prior authorization) by a Department representative.

Section 51315.1, Requirements Applicable to the Prior Authorization of Orthotic Appliances and Services, is adopted to:

1. [Introductory statement] Establish a lead-in for this section that specifies prior authorization for orthotics is based upon the supporting documentation and all other requirements set forth under Section 51315, as well as under this section.
2. [Subsection (a)] Establish that shoe supplies for diabetics include shoes and their fitting(s), modifications, and inserts; and shall be authorized when the patient has a diagnosis of diabetes mellitus and requires a specialized shoe(s), shoe modification(s) or shoe insert(s) to accommodate for or prevent foot ulceration and related foot conditions, such as one of the medical conditions listed in subsections (a)(1)(A) through(G) and (a)(2)(A) through (C), depending upon whether a prefabricated or a custom-made shoe(s), shoe insert(s) or modification(s) is being requested. These specialized shoes, shoe inserts, and shoe modifications are designed, developed, and marketed especially for diabetics and their unique set of foot problems and conditions. As such, requiring the patient be diagnosed with diabetes and a diabetes related foot condition(s) is appropriate for utilization review for the prior authorization of these shoes, shoe inserts, or shoe modifications. Subsection (a)(2)(C) is adopted to allow for the prior authorization for other related foot conditions not included under subsections (a)(2)(A) and (B), ensuring patients with other medical conditions have access to these custom-made shoe(s), shoe insert(s) or modification(s).
3. [Subsection (b)] Establish that compression burn garments shall be authorized when the patient requires a custom-fabricated garment to provide physician-ordered compression to facilitate the healing of burn tissue or similar injury or to prevent scarring. These specialized burn garments are designed, developed, and marketed especially for burn patients and their unique problems of burn tissue healing. As such, requiring the patient be diagnosed with a burn or similar injury that requires physician-ordered compression, is appropriate for utilization review for the prior authorization of these garments. The degree of compression

must be specified by the physician, because different burns and similar injuries require different degrees of compression for healing or prevention of scarring.

4. [Subsection (c)] Establish that gradient compression stockings include custom-made stockings and garter belts, and shall be authorized when one or both of the conditions specified in subsections (c)(1) and (2) are met. The gradient compression stockings shall be authorized for patients with symptomatic venous insufficiency or lymphedema in one or both lower extremities [(c)(1)]. The garter belts shall be authorized for patients who have an existing or authorized compression stocking or residual limb shrinker and require the use of a garter belt to hold the compression stocking or shrinker in place [(c)(2)]. Gradient compression stockings and garter belts are designed, developed, and marketed especially for patients with the above conditions. As such, requiring the patient be diagnosed with a medical condition that requires compression stockings or a garter belt, is appropriate for utilization review for the prior authorization of these items.
5. [Subsection (d)] Establish that subsections (d)(1) through (7) make up a group of appliances called “spinal orthoses.”
6. [Subsection (d)(1)] Establish that cranial orthoses shall be authorized when cranial molding is required in children two years of age and younger with plaglocephaly or craniosynostosis. These specialized cranial orthoses are designed, developed, and marketed especially for young children with the specified conditions that require these treatments. As such, requiring the patient be diagnosed with a medical condition that requires a specialized appliance, is appropriate for utilization review for the prior authorization of these appliances. The age requirement specified in subsection (d)(1) reflects the fact that after the age of two, cranial sutures are closed on a child’s head and molding is no longer possible without surgery. This subsection also states, for the purpose of cranial molding in children, the appliance must be manufactured by a Federal Drug Administration (FDA) approved laboratory. This ensures the appliance meets federal FDA criteria and is more likely to accomplish the necessary molding without further harm to the child. Additional information may be found on the FDA website, www.fda.gov.
7. [Subsection (d)(2)] Establish that cervical and multiple post collar orthoses (collars) shall be authorized when the patient has a medical condition listed in subsections (d)(2)(A) through (E) that requires support to the cervical spine to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized collars are designed, developed, and marketed especially for patients with the listed medical conditions that require cervical support with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires support to the cervical spine, is appropriate for utilization review for the prior authorization of these collars. Subsection (d)(2)(E) is adopted to allow for the prior authorization for other related medical conditions not included under subsections (d)(2)(A) through (D), ensuring patients with other medical conditions also have access to these collars.

8. [Subsection (d)(3)] Establish that thoracic orthoses (rib belts) shall be authorized when the patient has a medical condition, such as fractured ribs or torn intercostal ligaments that requires support to the thoracic area to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized rib belts are designed, developed, and marketed especially for patients with the described medical conditions that require thoracic support with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires support to the thoracic area, is appropriate for utilization review for the prior authorization of these rib belts.
9. [Subsection (d)(4)] Establish that thoracic orthoses (anterior-posterior-lateral-rotary control) shall be authorized when the patient has one of the medical conditions listed in subsections (d)(4)(A)1. through 4. that requires one or more of the treatments listed in subsections (d)(4)(B)1. through 3., to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized thoracic orthoses are designed, developed, and marketed especially for patients with the listed medical conditions that require one or more of the listed treatments with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires a specified treatment, is appropriate for utilization review for the prior authorization of these thoracic orthotics. Subsection (d)(4)(A)4., is adopted to allow for the prior authorization for other related medical conditions not included under subsections (d)(4)(A)1. through 3., ensuring patients with other conditions have access to these orthoses.
10. [Subsection (d)(5)] Establish that thoracic orthoses (triplanar control – modular segmented spinal system [prefabricated]) shall be authorized when the patient has one of the medical conditions listed in subsections (d)(5)(A)1. through 4., that requires one or both of the treatments listed in subsections (d)(5)(B)1. and 2., to decrease pain, to increase functional capacity or to prevent or ameliorate further injury. These specialized thoracic orthoses are designed, developed, and marketed especially for patients with the listed medical conditions that require one or both of the listed treatments with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires a specified treatment, is appropriate for utilization review for the prior authorization of these thoracic orthoses. Subsection (d)(5)(A)4., is adopted to allow for the prior authorization for other related medical conditions not included under subsections (d)(5)(A)1. through 3., ensuring patients with other conditions also have access to these orthoses.
11. [Subsection (d)(6)] Establish that thoracic orthoses (triplanar control – rigid frame) shall be authorized when the patient has a medical condition that requires one or more of the treatments listed in subsections (d)(6)(A) through (C) to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized thoracic orthoses are designed, developed, and marketed especially for patients with a medical condition that requires one or more of the listed treatments with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires a

specified treatment, is appropriate for utilization review for the prior authorization of these thoracic orthoses.

12. [Subsection (d)(7)] Establish that thoracic orthoses (triplanar control – rigid plastic shell) shall be authorized when the patient has one of the listed medical conditions listed in subsections (d)(7)(A) through (C) that requires reduction of gross trunk motion in three planes, when spinal support and immobilization are required to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized thoracic orthoses are designed, developed, and marketed especially for patients with one or more of the listed medical conditions that requires reduction of gross trunk motion in three planes with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires reduction of gross trunk motion, is appropriate for utilization review for the prior authorization of these thoracic orthoses.
13. [Subsection (e)] Establish that thoracic orthoses (sagittal or sagittal-coronal control) shall be authorized when the patient has a medical condition that requires one or more of the treatments listed in subsections (e)(1) through (3) to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized thoracic orthoses are designed, developed, and marketed especially for patients with a medical condition that requires one or more of the listed treatments with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires a specified treatment, is appropriate for utilization review for the prior authorization of these thoracic orthoses.
14. [Subsection (f)] Establish that subsections (f)(1) through (4) make up a group of appliances called “cervical-thoracic-lumbar-sacral orthoses.”
15. [Subsection (f)(1)] Establish that sacroiliac orthoses shall be authorized when the patient has a medical condition that requires one or more of the treatments listed in subsections (f)(1)(A) through (C) to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized orthoses are designed, developed, and marketed especially for patients with a medical condition that requires one or more of the listed treatments with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires a specified treatment, is appropriate for utilization review for the prior authorization of these orthoses.
16. [Subsection (f)(2)] Establish that lumbar orthoses shall be authorized when the patient has a medical condition that requires one or more of the treatments listed in subsections (f)(2)(A) through (D) to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized orthoses are designed, developed, and marketed especially for patients with a medical condition that requires one or more of the listed treatments with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires a specified treatment, is appropriate for utilization review for the prior authorization of these orthoses.
17. [Subsection (f)(3)] Establish that lumbar-sacral orthoses shall be authorized when the patient has a medical condition that requires one or more of the

treatments listed in subsections (f)(3)(A) through (E) to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized orthoses are designed, developed, and marketed especially for patients with a medical condition that requires one or more of the listed treatments with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires a specified treatment, is appropriate for utilization review for the prior authorization of these orthoses.

18. [Subsection (f)(4)] Establish that anterior-posterior-lateral control orthoses shall be authorized when the patient has a medical condition that requires support and maximum external restriction of anterior, posterior, and lateral motion to the cervical, thoracic, lumbar, and sacral spine to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized orthoses are designed, developed, and marketed especially for patients with a medical condition that requires support and complete external restriction of anterior, posterior and lateral motion to the cervical, thoracic, lumbar and sacral spine with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires support and maximum external restriction of anterior, posterior, and lateral motion to the cervical, thoracic, lumbar, and sacral spine, is appropriate for utilization review for the prior authorization of these orthoses.
19. [Subsection (g)] Establish that halo procedures include the base appliance and additions, and shall be authorized when one or both of the criteria specified in subsections (g)(1) and (2) are met. Base appliances shall be authorized when the patient has a medical condition that requires support and maximum external restriction of anterior, posterior and lateral motion to the cervical, thoracic, lumbar and sacral spine to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury [(g)(1)]. These specialized orthoses are designed, developed, and marketed especially for patients with a medical condition that requires support and maximum external restriction of anterior, posterior, and lateral motion to the cervical, thoracic, lumbar, and sacral spine with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires support and maximum external restriction of anterior, posterior, and lateral motion to the cervical, thoracic, lumbar, and sacral spine, is appropriate for utilization review for the prior authorization of these halo procedures. Additions shall be authorized when all of the listed criteria are met [(g)(2)(A) through (C)].

    *These requirements for the prior authorization of additions are consistent throughout this proposed regulatory action. Specifically, the patient's medical condition must require the specific function for which the addition(s) was designed. The addition(s) must be necessary to improve the functionality of the base appliance, without which the patient's medical need(s) would not be met. If the patient's medical need(s) is not met with the addition(s), the purchase would serve no useful purpose and represent an unnecessary expenditure under Medi-Cal. The patient must have an existing or authorized base appliance that is

compatible with the addition(s). Incompatibility between the base appliance and the addition(s) would result in the appliance being non-functional.
*These requirements for additions are necessary to determine the addition(s) is medically necessary for the patient and it represents an appropriate expenditure under Medi-Cal.

20. [Subsection (h)] Establish that additions to spinal orthoses shall be authorized when all of the criteria specified in subsections (h)(1) through (3) are met. These requirements for the prior authorization of additions are consistent throughout this proposed regulatory action (see number 19* above). These requirements for additions are necessary to determine the addition(s) is medically necessary for the patient and represent an appropriate expenditure under Medi-Cal.
21. [Subsection (i)] Establish that subsections (i)(1) through (4) make up a group of appliances called “orthotic devices-scoliosis procedures.”
22. [Subsection (i)(1)(A)] Establish that cervical-thoracic-lumbar-sacral orthoses shall include the appliances listed in (i)(1)(A)1. through 3.
23. [Subsection (i)(1)(A)1] Establish that the Infant Immobilizer shall be authorized when the child is under one year of age and requires stabilization of the cervical spine, upper thoracic spine, and airway. The infant immobilizer will not be authorized for use in restraining infants during surgical or radiological procedures. This highly specialized orthosis is designed, developed, and marketed especially for small infants that require “immobilization” of the upper body due to a condition(s) of the cervical spine, upper thoracic spine, or airway. This orthosis will not be authorized for restraint purposes only, as there are other devices considerably more cost effective for restraining an infant for procedures. Providers will often purchase many of the less costly devices that can then be used on an as needed basis. The age consideration reflects the condition(s) being treated and that such a condition(s) rarely occurs after one year of age. The age consideration also reflects the size of the infant immobilizer and the fact that larger children will not fit the device.
24. [Subsection (i)(1)(A)2.] Establish that the tension based scoliosis orthosis shall be authorized when the child is diagnosed with adolescent idiopathic scoliosis. This highly specialized orthosis is designed, developed, and marketed especially for this condition of adolescence and is not an appropriate device for any other population or condition. As such, requiring the patient be diagnosed with adolescent idiopathic scoliosis is appropriate for utilization review for the prior authorization of this orthosis.
25. [Subsection (i)(1)(A)3.] Establish that additions shall be authorized when all the listed criteria are met [(i) (1)(A)3.a. through c.]. These requirements for the prior authorization of additions are consistent throughout this proposed regulatory action (see number 19* above). These requirements for additions are necessary to determine the addition(s) is medically necessary for the patient and represent an appropriate expenditure under Medi-Cal.
26. [Subsection (i)(1)(B)] Establish that cervical-thoracic-lumbar-sacral orthoses or scoliosis orthoses shall be authorized when the criteria specified in subsections (i)(1)(B)1. and 2. are met. The orthosis shall be authorized when the patient has a diagnosis of scoliosis or other curvature or instability of the spine [(i)(1)(B)1.]

and the appliance is appropriate to the patient's degree and type of scoliosis or spinal curvature or instability in which the degree of spinal curvature or instability, any lower extremity length discrepancy, and goals of treatment are considered [(i)(1)(B)2.]. These specialized appliances are designed, developed, and marketed for patients with scoliosis or other curvature or instability of the spine. As such, requiring the patient be diagnosed with scoliosis or other curvature or instability of the spine, and that the appliance is appropriate to the specific patient and requires a specified treatment, is appropriate for utilization review for the prior authorization of these orthoses.

27. [Subsection (i)(2)] Establish that thoracic-lumbar-sacral orthoses (low profile) includes the base appliance and additions, and shall be authorized when one or both of the criteria specified in subsections (i)(2)(A) and (B) is met. The base appliance shall be authorized when the patient has a diagnosis of scoliosis or other curvature or instability of the spine [(i)(2)(A)1.] and the appliance is appropriate to the patient's degree and type of scoliosis or spinal curvature or instability in which the degree of spinal curvature or instability, any lower extremity length discrepancy, and goals of treatment are considered [(i)(2)(A)2.]. These specialized appliances are designed, developed, and marketed for patients with scoliosis or other curvature or instability of the spine. As such, requiring the patient be diagnosed with scoliosis or other curvature or instability of the spine, and the appliance is appropriate to the specific patient and requires a specified treatment, is appropriate for utilization review for the prior authorization of these orthoses. The requested addition(s) shall be authorized when all of the criteria specified in subsections (i)(2)(B)1. through 4., are met. Because these are additions to base appliances, especially made for patients with scoliosis or other curvature or instability of the spine, such a diagnosis for the addition(s) is appropriate [(i)(2)(B)1.]. These requirements for the prior authorization of additions [(i)(2)(B) 2. through 4.] are consistent throughout this proposed regulatory action (see number 19* above). These requirements for additions are necessary to determine the addition(s) is medically necessary for the patient and represent an appropriate expenditure under Medi-Cal.
28. [Subsection (i)(3)] Establish that other scoliosis procedures (body jackets) shall be authorized when both of the criteria specified in subsections (i)(3)(A) and (B) are met. The orthotic appliance shall be authorized when the patient has a diagnosis of scoliosis or other curvature or instability of the spine [(i)(3)(A)] and the appliance is appropriate to the patient's degree and type of scoliosis or spinal curvature or instability in which the degree of spinal curvature or instability, any lower extremity length discrepancy, and goals of treatment are considered [(i)(3)(B)]. These specialized orthoses are designed, developed, and marketed for patients with scoliosis or other curvature or instability of the spine. As such, requiring the patient be diagnosed with scoliosis or other curvature or instability of the spine, and the appliance is appropriate to the specific patient and requires a specified treatment, is appropriate for utilization review for the prior authorization of these orthoses.
29. [Subsection (j)] Establish that subsections (j)(1) through (10) make up a group of appliances called "orthotic devices–lower limb (extremity)."

30. [Subsection (j)(1)] Establish that hip orthoses–flexible shall be authorized when the patient has one or both of the medical conditions listed in subsections (j)(1)(A)1. through 4., that requires one of the treatments listed in subsections (j)(1)(B)1. through 3., to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized hip orthoses are designed, developed, and marketed especially for patients with the listed medical conditions that require one or both of the listed treatments with the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires a specified treatment is appropriate for utilization review for the prior authorization of these hip orthoses. Subsection (j)(1)(A)4., is adopted to allow for the prior authorization for other related medical conditions not included under subsections (j)(1)(A)1. through 3., ensuring patients with other conditions also have access to these specialized hip orthoses.
31. [Subsection (j)(2)] Establish that Legg Perthes orthoses shall be authorized when the patient has a diagnosis of Legg-Calve-Perthes deformity or similar deformity or disease, and requires control of hip abduction, adduction or weight bearing. These specialized lower limb orthoses are designed, developed, and marketed especially for patients with Legg-Perthes deformity or similar deformity or disease, who require a lower limb orthosis with the specified goals of treatment. As such, requiring the patient be diagnosed with Legg-Perthes deformity or similar deformity or disease that requires a lower limb orthoses, is appropriate for utilization review for the prior authorization of these orthoses.
32. [Subsection (j)(3)] Establish that knee orthoses shall be authorized when the patient has a deformity or injury of, or affecting the knee, such as one of the medical conditions listed in subsections (j)(3)(A)1. through 6., that requires one or more of the treatments listed in subsections (j)(3)(B)1. through 6., to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized knee orthoses are designed, developed, and marketed especially for patients with a deformity or injury of, or affecting the knee that requires one of the listed treatments with the specified goals of treatment. As such, requiring the patient be diagnosed with such a deformity or injury that requires a specified treatment, is appropriate for utilization review for the prior authorization of these knee orthoses. Subsection (j)(3)(A)6., is adopted to allow for the prior authorization for other related medical conditions not included under subsections (j)(3)(A)1. through 5., ensuring patients with other conditions also have access to these knee orthoses.
33. [Subsection (j)(4)] Establish that ankle-foot orthoses shall be authorized when the patient has a disease, deformity, injury, or condition of, or affecting the lower extremity in which the patient experiences pain or diminished functional capacity of the lower extremity and requires one or more of the treatments listed in subsections (j)(4)(A) through (E). These specialized ankle-foot orthoses are designed, developed, and marketed especially for patients with a disease, deformity, injury, or condition of, or affecting the lower extremity in which the patient experiences pain or diminished functional capacity of the lower extremity and requires one or more of the specified treatments. As such, requiring the patient be diagnosed with such a disease, deformity, or injury that requires a

specified treatment, is appropriate for utilization review for prior authorization of these ankle-foot orthoses.

34. [Subsection (j)(5)] Establish that knee-ankle-foot orthoses, or any combination, shall be authorized when the patient has a disease, deformity, injury, or condition of, or affecting the knee or ankle joint(s) in which the patient experiences pain or diminished functional capacity of the knee or ankle joint(s) and requires one or more of the treatments listed in subsections (j)(5)(A) through (C). These specialized knee-ankle-foot orthoses are designed, developed, and marketed especially for patients with a disease, deformity, injury, or condition of, or affecting the knee or ankle joint(s) in which the patient experiences pain or diminished functional capacity of the knee or ankle joint(s) and requires one or more of the specified treatments. As such, requiring the patient be diagnosed with such a disease, deformity, or injury that requires a specified treatment, is appropriate for utilization review for the prior authorization of these knee-ankle-foot orthoses.
35. [Subsection (j)(6)] Establish that torsion control: hip-knee-ankle-foot orthoses shall be authorized when the patient has a disease, deformity, injury, or condition of, or affecting the hip, knee or ankle joint(s) in which the patient experiences pain or diminished functional capacity of the hip, knee or ankle joint(s) and requires control in rotation of one or both hips. These specialized hip-knee-ankle-foot orthoses are designed, developed and marketed especially for patients with a disease, deformity, injury, or condition of, or affecting the hip, knee or ankle joint(s) in which the patient experiences pain or diminished functional capacity of the hip, knee or ankle joint(s) and requires control in rotation of one or both hips. As such, requiring the patient be diagnosed with such a disease, deformity, or injury that requires control in rotation of one or both hips, is appropriate for utilization review for the prior authorization of these hip-knee-ankle-foot orthoses.
36. [Subsection (j)(7)] Establish that torsion control: hip-knee-ankle-foot orthoses (tibial fracture casts) shall be authorized when the patient has a fracture of the tibia or fibula and requires support and stabilization of the fracture site to facilitate healing, to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized fracture casts (orthoses) are designed, developed, and marketed especially for patients with a fracture of the tibia or fibula that requires support and stabilization of the fracture site to meet the specified goals of treatment. As such, requiring the patient be diagnosed with such a fracture of the tibia or fibula that requires support and stabilization of the fracture site, is appropriate for utilization review for the prior authorization of these fracture casts.
37. [Subsection (j)(8)] Establish that torsion control: hip-knee-ankle-foot orthoses (femoral fracture casts) shall be authorized when the patient has a fracture of the femur and requires support and stabilization of the fracture site to facilitate healing, to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized fracture casts (orthoses) are designed, developed, and marketed especially for patients with a fracture of the femur that requires support and stabilization of the fracture site to meet the

specified goals of treatment. As such, requiring the patient be diagnosed with such a fracture of the femur that requires support and stabilization of the fracture site, is appropriate for utilization review for the prior authorization of these fracture casts.

38. [Subsection (j)(9)] Establish that reciprocating gait orthoses shall be authorized when chronologically and developmentally appropriate and meets all of the criteria specified in subsections (j)(9)(A) through (C). The requirement the patient be chronologically and developmentally appropriate is necessary, because these orthoses are not designed for the very small bodies of very young children; and children who are not developmentally appropriate are usually not ambulatory and therefore would not be able to, nor need to use the reciprocating gait orthosis. The patient must have both of the medical conditions specified in subsections (j)(9)(A)1. and 2. Reciprocating gait orthoses are designed, developed, and marketed especially for patients with thoracic or upper lumbar spine lesions with spasticity [(j)(9)(A)1.] and range of motion limitations that nevertheless allow joints to be put in the appropriate position for ambulation. If the joint(s) is not able to be placed in a position for ambulation, the orthosis will not correct the problem or allow ambulation. The patient must not have any of the medical conditions or contraindications specified in subsections (j)(9)(B)1. through 8. These conditions and contraindications will preclude effective use of the reciprocating gait orthosis.
39. Subsection (j)(9)(B)1., precludes prior authorization for reciprocating gait orthoses when the patient has severe irreducible contractures that would prevent the patient from establishing normal body alignment.
40. Subsection (j)(9)(B)2., precludes prior authorization for reciprocating gait orthoses when the patient has severe spasticity or other involuntary muscle activity that would prevent free and coordinated mobility.
41. Subsection (j)(9)(B)3., precludes prior authorization for reciprocating gait orthoses when the patient is severely obese, preventing the patient from being able to appropriately use the orthosis due to excessive body weight.
42. Subsection (j)(9)(B)4., precludes prior authorization for reciprocating gait orthoses when the patient has poor upper extremity strength preventing the patient from using the orthosis since normal upper body strength is necessary for balance and alignment.
43. Subsection (j)(9)(B)5., precludes prior authorization for reciprocating gait orthoses when the patient has advanced osteoporosis preventing the patient from using the orthosis because of fragile bones subject to easy breaks and decreased upper body strength.
44. Subsection (j)(9)(B)6., precludes prior authorization for reciprocating gait orthoses when the patient has a fracture(s) or a history of fracture(s), because the patient would be subject to easy breaks and decreased upper body strength.
45. Subsection (j)(9)(B)7., precludes prior authorization for reciprocating gait orthoses when the patient has a documented history of noncompliance preventing effective use of the orthosis and causing further harm to the patient when instructions are not followed.

46. Subsection (j)(9)(B)8., precludes prior authorization for reciprocating gait orthoses when the patient has a pressure sore(s) in an area(s) that would be in contact with the orthoses causing significant new harm to the patient and would eventually preclude any use of the orthosis.
47. Subsections (j)(9)(C)1. through 7. These subsections represent the general health of the patient and provide reasonable assurance the orthosis will be operational for the patient. These criteria are necessary to ensure the orthosis will be the correct appliance for the patient and unnecessary and more costly appliances are not authorized.
48. Subsection (j)(9)(C)1., requires documentation that supports cardiopulmonary integrity. These orthoses require significant stamina to use effectively. Documentation of cardiopulmonary integrity ensures the patient will be able to consistently use the orthosis.
49. Subsection (j)(9)(C)2., requires documentation that no other orthosis will meet the patient's medical need(s). This requirement is consistent with Section Section 51003(f) and precludes Medi-Cal from paying for an appliance that exceeds the patient's needs and is more costly.
50. Subsection (j)(9)(C)3., requires documentation that the patient's spinal cord injury is above L3. These orthoses are designed and developed to assist patients with high spinal cord injuries that otherwise cannot ambulate. There is more cost effective equipment for patients with lower injuries.
51. Subsection (j)(9)(C)4., requires documentation that the patient has no contractures and muscle atrophy preventing the patient from establishing normal body alignment.
52. Subsection (j)(9)(C)5., requires documentation that supports stability of the spine. These orthoses require significant stamina and strength to use effectively. Documentation of spinal stability ensures the patient will be able to consistently use the orthosis.
53. Subsection (j)(9)(C)6., requires documentation that the patient has no advanced osteoporosis or fracture(s) preventing the patient from using the orthoses, because of fragile bones subject to easy breaks and decreased upper body strength.
54. Subsection (j)(9)(C)7., requires documentation of one of the listed diagnoses. These orthoses are designed and developed specifically for patients with these diagnoses, so this documentation ensures the patient requires the specific orthosis.
55. Subsections (j)(9)(D)1. through 5., specify additional criteria for the patient 21 years of age and older and is necessary because the reciprocating gait orthosis becomes more difficult to use and benefit from as the body becomes older and less flexible. These additional criteria will ensure an older patient is well suited for, and motivated to use these complicated orthoses.
56. [Subsection (j)(10)] Establish that additions to lower extremity orthoses include the specific appliances listed in subsections (j)(10)(A)1. through 7., and shall be authorized when all of the criteria in subsections (j)(10)(B)1. through 3., are met. These requirements for the prior authorization of additions are consistent throughout this proposed regulatory action (see number 19* above). These

requirements for additions are necessary to determine the addition(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal. Subsection (j)(10)(C) is necessary to outline additional criteria for custom foot orthoses. This fabrication specification is necessary to ensure the custom foot orthosis meets minimal standards so the patient receives the specific appliance that will meet his/her medical need(s), and there are no unnecessary expenditures, on inferior fabrication methods, under Medi-Cal.

57. [Subsection (k)] Establish that subsections (k)(1) through (4) make up a group of appliances called “orthopedic shoes.”
58. [Subsection (k)(1)] Establish that Hallus-Valgus splints shall be authorized when the patient has a medical condition of the foot that requires a custom-fitted orthosis to hold the big toe in the proper anatomical position. These specialized splints are designed, developed, and marketed especially for patients with a medical condition of the foot that requires the big toe be held in the proper anatomical position. As such, requiring the patient be diagnosed with such a medical condition that requires a custom-fitted orthoses, is appropriate for utilization review for the prior authorization of these splints.
59. [Subsection (k)(2)] Establish that abduction and rotation bars shall be authorized when the patient has a medical condition of the foot (feet) that requires one or both of the treatments listed in subsections (k)(2)(A) and (B) to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized appliances are designed, developed, and marketed for patients with a medical condition of the foot (feet) that requires one or both of the listed treatments to meet the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires a specified treatment, is appropriate for utilization review for the prior authorization of these orthoses.
60. [Subsection (k)(3)] Establish that subsections (k)(3)(A) and (B) make up a group of appliances called “orthopedic footwear.”
61. [Subsection (k)(3)(A)] Establish that stock orthopedic shoes and stock conventional shoes include in-depth shoes and shall be authorized when the criteria specified in subsections (k)(3)(A)1. and 2., are met. Subsection (k)(3)(A)1., specifies that at least one of the shoes must be attached to a prosthesis or brace. “Brace” and “attached to a prosthesis or brace” are defined in subsections (k)(3)(A)1.a. and b. These definitions are widely accepted in the O&P field of medicine and serve to define precisely what will be authorized under Medi-Cal. These definitions serve to set a standard to ensure a high quality appliance and to prevent further harm to the patient that might occur if a lesser standard were applied. Medi-Cal does not reimburse for stock shoes when they are furnished with no attachment or modification. When at least one of the shoes is attached to a prosthesis or brace or the shoe is modified [subsection (k)(4)] the shoe becomes a medical appliance rather than footwear. Subsection (k)(3)(A)2., specifies the patient must have a medical condition of the foot (feet) that requires one or more of the treatments listed in subsections (k)(3)(A)2. a. through f. These specialized shoes are designed, developed and marketed for patients with a medical condition of the foot (feet), as described in subsection (k)(3)(A)2., that

requires one or more of the treatments listed in subsection (k)(3)(A)2.a.through f., to meet the specified goals of treatment. As such, requiring the patient be diagnosed with such a medical condition that requires a specified treatment, is appropriate for utilization review for the prior authorization of these shoes.

62. [Subsection (k)(3)(B)] Establish that custom-made orthopedic shoes include both the base shoe(s) and any required addition(s).
63. [Subsection (k)(3)(B)1.] Establish that custom-made orthopedic shoes shall be authorized when the patient does not require a shoe provided under the diabetic footwear program [subsection (a)] but whose medical need(s) cannot be met by modification(s) to a stock orthopedic or stock conventional shoe(s) [subsections (k)(3)(A) and (k)(4)]. This subsection requires the prescribing practitioner document the nature, cause, and severity of the foot problem that substantiates the requirement for a custom-made shoe(s), such as one of the medical conditions listed in subsections (k)(3)(B)1.a.i., through iv., that requires one or more of the accommodations listed in subsections (k)(3)(B)1.b.i. through iv. These specialized orthopedic shoes are designed, developed, and marketed for patients with a medical condition of the foot, such as one of the medical conditions listed that requires one or more of the listed accommodations. As such, requiring the patient be diagnosed with such a medical condition is appropriate for utilization review for the prior authorization of these orthoses. Subsection (k)(3)(B)1.a.iv., is adopted to allow for medical conditions not included under subsections (k)(3)(B) 1.a.i. through iii. and b.i. through iii., ensuring patients with other conditions also have access to these orthopedic shoes.
64. [Subsection (k)(3)(B)2.] Establish that a custom-made orthopedic shoe shall be authorized when it has all of the characteristics specified in subsections (k)(3)(B)2.a. through e. These requirements will ensure a high quality shoe(s) and will prevent further injury to the patient that might occur if a lower quality shoe(s) were authorized.
65. [Subsection (k)(3)(B)3.] Establish that the additions to the base shoe shall be authorized when all of the criteria specified in subsections (k)(3)(B) 3.a. through c., are met. These requirements for the prior authorization of additions are consistent throughout this proposed regulatory action (see number 19* above). These requirements for additions are necessary to determine the addition(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.
66. [Subsection (k)(4)] Establish that shoe modifications include all of the additions, modifications and services listed in subsections (k)(4)(A)1. through 5., and shall be authorized when all of the criteria specified in subsections (k)(4)(B)1. through 3., are met. Subsection (k)(4)(A)5., includes a definition for the terms “transfer” and “replacement” as they relate to shoe modifications of stock orthopedic shoes and stock conventional shoes. These definitions are widely accepted in the O&P field of medicine and serve to define precisely what will be authorized under Medi-Cal. These definitions serve to set a standard to ensure a high quality appliance and to prevent further harm to the patient that might occur if a lesser standard were applied.

67. [Subsection (k)(4)(B)] Establish that the addition(s), modification(s) or service(s) to the shoe(s) shall be authorized when all of the criteria specified in subsections (k)(4)(B)1. through 3., are met. These requirements for the prior authorization of addition(s), modification(s), or service(s) are consistent throughout this proposed regulatory action (see number 19* above). These requirements for addition(s), modifications(s), or service(s) are necessary to determine the addition(s), modifications(s), or service(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.
68. [Subsection (l)] Establish that subsections (l)(1) through (7) make up a group of appliances called “orthotic devices–upper limb.”
69. [Subsection (l)(1)] Establish that shoulder orthoses shall be authorized when the patient has a medical condition of, or affecting the shoulder joint, that requires the shoulder be held in place to prevent or limit motion to protect the shoulder joint from injury or provide support/stabilization during functional activities. These specialized shoulder orthoses are designed, developed, and marketed for patients with a medical condition of, or affecting the shoulder joint that requires the shoulder be held in place to prevent or limit motion to protect the shoulder joint from injury or provide support/stabilization during functional activities. As such, requiring the patient be diagnosed with such a medical condition that requires protection/support/stabilization of the shoulder joint, is appropriate for utilization review for the prior authorization of these shoulder orthoses.
70. [Subsection (l)(2)] Establish that elbow orthoses includes elbow orthoses, elbow-wrist-hand orthoses, and elbow-wrist-hand-finger orthoses and shall be authorized when the patient has a medical condition of, or affecting one or more of the listed joints that requires support, stabilization, restriction, or enhancement of movement of one or more of the listed joints to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized elbow orthoses are designed, developed, and marketed for patients with a medical condition of, or affecting one or more of the listed joints that requires support, stabilization, restriction, or enhancement of movement of one or more of the listed joints. As such, requiring the patient be diagnosed with such a medical condition is appropriate for utilization review for the prior authorization of these elbow orthoses.
71. [Subsection (l)(3)] Establish that wrist-hand-finger orthoses shall be authorized when the patient has a medical condition of, or affecting one or more of the listed joints that requires support, stabilization, restriction, or enhancement of movement of one or more of the listed joints to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized wrist-hand-finger orthoses are designed, developed, and marketed for patients with a medical condition of, or affecting one or more of the listed joints that requires support, stabilization, restriction, or enhancement of movement of one or more of the listed joints. As such, requiring the patient be diagnosed with such a medical condition is appropriate for utilization review for the prior authorization of these wrist-hand-finger orthoses.
72. [Subsection (l)(4)] Establish that additions to upper limb orthoses shall be authorized when all of the criteria listed in subsections (l)(4)(A) through (C) are

met. These requirements for the prior authorization of addition(s) are consistent throughout this proposed regulatory action (see number 19* above). These requirements for addition(s) are necessary to determine the addition(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.

73. [Subsection (l)(5)] Establish that dynamic flexor hinge, reciprocal wrist extension/flexion, and finger flexion/extension orthoses shall be authorized when the patient has a medical condition of, or affecting the wrist, hand or finger(s) that requires a custom-made orthosis to hold the hand, finger or wrist in a prescribed position and to enhance and control movement of the hand, finger or wrist. These specialized orthoses are designed, developed, and marketed for patients with a medical condition of, or affecting the wrist, hand or finger(s) that requires a custom-made orthosis to hold the hand, finger or wrist in a prescribed position and to enhance and control movement of the hand, finger or wrist. As such, requiring the patient be diagnosed with such a medical condition is appropriate for utilization review for the prior authorization of these orthoses.
74. [Subsection (l)(6)] Establish that externally powered wrist-hand-finger orthoses shall be authorized when the patient has a medical condition of, or affecting the wrist, hand or finger(s) that requires a custom-made, electrically powered wrist-hand-finger orthosis to allow effective movement of the wrist, hand or finger(s) in the performance of ADLs or IADLs [(l)(6)(A)] and when the patient cannot otherwise effectively use a manually operated orthosis [(l)(6)(B)]. These specialized, electrically powered orthoses are designed, developed, and marketed for patients with a medical condition of, or affecting the wrist, hand or finger(s) that precludes the use of a manual orthosis and requires a custom-made electrically powered orthosis to allow effective movement of the wrist, hand or finger(s). As such, requiring that the patient be diagnosed with such a medical condition and not being able to use a manually operated orthosis is appropriate for utilization review for the prior authorization of these orthoses. The use of ADLs and IADLs as the benchmark is consistent with the discussion under Section 51315(c)(2).
75. [Subsection (l)(7)] Establish that subsections (l)(7)(A) and (B) make up a group of appliances called “other wrist-hand-finger orthoses–custom fitted.”
76. [Subsection (l)(7)(A)] Establish that custom fitted wrist-hand-finger orthoses shall be authorized when the patient has a medical condition of, or affecting the wrist, hand or finger(s) that requires a custom-fitted orthosis to provide support, stabilization, restriction, or enhancement of movement of the wrist, hand or finger(s). These specialized custom fitted orthoses are designed, developed, and marketed for patients with a medical condition of, or affecting the wrist, hand or finger(s) that requires a custom-fitted orthosis to provide support, stabilization, restriction, or enhancement of movement of the wrist, hand or finger(s). As such, requiring the patient be diagnosed with such a medical condition is appropriate for utilization review for the prior authorization of these orthoses.
77. [Subsection (l)(7)(B)] Establish that the addition of a joint(s) to an upper extremity orthosis shall be authorized when all of the criteria specified in subsections (l)(7)(B)1. through 3., are met. These requirements for the prior authorization of

an addition of a joint are consistent throughout this proposed regulatory action (see number 19* above). These requirements for an addition of a joint are necessary to determine the addition is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.

78. [Subsection (m)] Establish that subsections (m)(1) through (4) make up a group of appliances called “shoulder-elbow-wrist-hand orthoses.”
79. [Subsection (m)(1)] Establish that abduction position, custom fitted orthoses shall be authorized when the patient has a medical condition of, or affecting the shoulder, elbow, wrist, or hand, such as one of the medical conditions listed in subsections (m)(1)(A)1. through 3.; and when the patient requires the orthosis to provide positioning, stabilization or restriction of movement of the shoulder, elbow, wrist, or hand [(m)(1)(B)]. These specialized custom fitted orthoses are designed, developed, and marketed for patients with a medical condition of, or affecting the shoulder, elbow, wrist, or hand such as one of the medical conditions listed in subsections (m)(1)(A)1. through 3., that requires an orthosis to provide positioning or restriction of movement of the shoulder, elbow, wrist, or hand. As such, requiring the patient be diagnosed with such a medical condition that requires positioning, stabilization, or restriction of movement of the shoulder, elbow, wrist, or hand, is appropriate for utilization review for the prior authorization of these orthoses. Subsection (m)(1)(A)3., is adopted to allow for conditions not included in the list found in subsections (m)(1)(A)1. and 2., ensuring patients with related medical conditions also have access to these orthoses.
80. [Subsection (m)(2)] Establish that mobile arm supports shall be authorized when the patient meets the criteria specified in subsection (m)(1) and uses a wheelchair. Mobile arm supports are designed specifically for those patients that would otherwise require an abduction position, custom-fitted orthosis, but requires the orthosis accommodate the use of a wheelchair.
81. [Subsection (m)(3)] Establish that additions to mobile arm supports include additions and adaptations to the mobile arm support or the addition(s) and shall be authorized when all of the criteria specified in subsections (m)(3)(A) through (C) are met. These requirements for the prior authorization of addition(s) or adaptation(s) are consistent throughout this proposed regulatory action (see number 19* above). These requirements for addition(s) or adaptation(s) are necessary to determine the addition(s) or adaptation(s) are medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.
82. [Subsection (m)(4)] Establish that fracture orthoses shall be authorized when the patient has a fracture of the upper extremity and requires support and stabilization of the fracture site to facilitate healing, to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury. These specialized orthoses are designed, developed, and marketed for patients with a fracture of the upper extremity that requires support and stabilization of the fracture site to meet the specified treatment goals. As such, requiring the patient be diagnosed with such a medical condition that requires support and stabilization to the fracture site, is appropriate for utilization review for the prior authorization of these orthoses.

83. [Subsection (n)] Establish that “repairs” include repairs, maintenance, replacements, and associated labor and shall be authorized when the criteria specified in subsections (n)(1) through (3) are met. The patient must have an existing orthosis that requires repair, maintenance, or replacement [(n)(1)]. The repair cost(s) must be less than the cost(s) of purchasing a new appliance [(n)(2)]. This will preclude the prior authorization for repair of appliances when the repair cost is equal to or greater than the cost of purchasing a new appliance. This restriction promotes cost effectiveness under Medi-Cal by prohibiting the unnecessary repair of appliances when it would be the same cost or less costly to purchase a new appliance. In addition, the request or claim must include a list of the components to be repaired or replaced and a statement explaining the necessity for the repair or replacement [(n)(3)] that supports utilization control under Medi-Cal. This requirement also ensures a thorough review of the details for orthotic appliance repair requests to ensure the repair or replacement is necessary to support a patient’s medical need(s) and supports cost effectiveness under Medi-Cal.
84. [Subsection (o)] Establish that ancillary orthotic devices shall be authorized when the patient has a medical condition that requires an upper or lower extremity orthosis not otherwise covered under this section to provide support and positioning to an upper or lower extremity joint(s). This subsection allows for prior authorization of an upper or lower limb orthotic appliances not specifically covered in this section to ensure patients that require support and positioning can have access to these ancillary orthotic devices.
85. [Subsection (p)] Establish that trusses shall be authorized when the patient has an abdominal hernia and requires a truss to reduce the hernia. Trusses are specifically designed for the reduction of abdominal hernias, either in conjunction with or in lieu of surgery. As such, requiring the patient have an abdominal hernia is appropriate for utilization review for the prior authorization of a truss.

<u>Section 51315.2, Requirements Applicable to the Prior Authorization of Prosthetic Appliances and Services, is adopted to:</u>

1. [Introductory statement] Establish a lead-in for this section that specifies prior authorization for prosthetics is based upon the supporting documentation and all other requirements set forth under Section 51315, as well as under this section.
2. [Subsection (a) and (a)(1)] Establish lower limb prostheses as an appliance that shall be authorized when the patient has a functional level of “one” or higher; and establish that these prostheses will not be authorized when the patient has a functional level of “zero”. Functional levels are a measurement of the patient’s potential to “function” in this case to ambulate or perform other functional activities. When the patient’s functional level is zero, it has been determined the patient will not be able to ambulate or perform other functional activities regardless of the assistance provided. Therefore, it would be an inappropriate expenditure to authorize a lower limb prosthesis for the patient with a functional level of zero.

3. [Subsection (a)(2)] Establish that subsections (a)(2)(A) through (N) make up a group of appliances called “lower limb prostheses.”
4. [Subsection (a)(2)(A)] Establish that partial foot prostheses shall be authorized when the patient has had an amputation of part or all of the foot and requires a definitive prosthesis to permit ambulation or other functional activities. This type of prosthesis is designed, developed, and marketed for patients with an amputation of part or all of the foot that requires a prosthesis to permit ambulation or other functional activities. As such, requiring that the patient has had such an amputation and requires a definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
5. [Subsection (a)(2)(B)] Establish that ankle prostheses shall be authorized when the patient has had an amputation through or at the ankle and requires a definitive prosthesis to permit ambulation or other functional activities. This type of prosthesis is designed, developed, and marketed for patients with an amputation through or at the ankle, such as a Syme’s procedure that requires a prosthesis to permit ambulation or other functional activities. As such, requiring that the patient has had such an amputation and requires a definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
6. [Subsection (a)(2)(C)] Establish that below knee prostheses shall be authorized when the patient has had an amputation between the ankle and knee and requires an exoskeletal definitive prosthesis to permit ambulation or other functional activities. This type of prosthesis is designed, developed, and marketed for patients with an amputation between the ankle and knee that requires a prosthesis to permit ambulation or other functional activities. As such, requiring that the patient has had such an amputation and requires an exoskeletal definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
7. [Subsection (a)(2)(D)] Establish that knee disarticulation prostheses shall be authorized when the patient has had an amputation through or near the knee and requires an exoskeletal definitive prosthesis to permit ambulation or other functional activities. This type of prosthesis is designed, developed, and marketed for patients with an amputation through or near the knee requiring a prosthesis to permit ambulation or other functional activities. As such, requiring that the patient has had such an amputation is appropriate for utilization review for the prior authorization of these prostheses.
8. [Subsection (a)(2)(E)] Establish that above knee prostheses shall be authorized when the patient has had an amputation between the knee and hip and requires a definitive prosthesis to permit ambulation or other functional activities. This type of prosthesis is designed, developed, and marketed for patients with an amputation between the knee and hip requiring a prosthesis to permit ambulation or other functional activities. As such, requiring that the patient has had such an amputation and requires a definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
9. [Subsection (a)(2)(F)] Establish that hip disarticulation prostheses shall be authorized when the patient has had an amputation through or near the hip and requires an exoskeletal definitive prosthesis to permit ambulation or other

functional activities. This type of prosthesis is designed, developed, and marketed for patients with an amputation through or near the hip requiring a prosthesis to permit ambulation or other functional activities. As such, requiring that the patient has had such an amputation and requires an exoskeletal definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.

10. [Subsection (a)(2)(G)] Establish that hemipelvectomy prostheses shall be authorized when the patient has had an amputation with removal of half the pelvis and requires an exoskeletal definitive prosthesis to permit ambulation or other functional activities. This type of prosthesis is designed, developed, and marketed for patients with an amputation with the removal of half the pelvis requiring a prosthesis to permit ambulation or other functional activities. As such, requiring that the patient has had such an amputation and requires an exoskeletal definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
11. [Subsection (a)(2)(H)] Establish that endoskeletal prostheses shall be authorized when the patient has had a lower limb amputation and requires an endoskeletal definitive prosthesis to permit ambulation or other functional activities. This type of prosthesis is designed, developed, and marketed for patients with an amputation of a lower limb requiring a prosthesis to permit ambulation or other functional activities. As such, requiring that the patient has had such an amputation and requires an endoskeletal definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
12. [Subsection (a)(2)(I)] Establish that immediate and early post-surgical procedures shall be authorized when the patient has had a lower limb amputation and requires one or more of the appliances/services listed in subsections (a)(2)(I)1. through 3. A temporary prosthesis shall be authorized when it is applied soon after amputation, before the wound has completely healed, to permit some lower extremity function [(a)(2)(I)1.]. This subsection also specifies a temporary prosthesis may be authorized when it is used after the original amputation or after a residual limb revision(s). An additional cast change(s) and realignment(s) of the temporary prosthesis specified in subsection (a)(2)(I)1., shall be authorized when the patient has an existing or authorized temporary prosthesis that requires these services [(a)(2)(I)2.]. A temporary application of a non-weight bearing rigid dressing shall be authorized when it is applied soon after amputation, before the wound has completely healed, and when there is no expectation of use of a prosthesis until the wound has completely healed [(a)(2)(I)3.]. This subsection also specifies a temporary prosthesis may be authorized when it is used after the original amputation or after a residual limb revision(s). Immediate and early post-surgical procedures are designed, developed, and marketed for patients with an amputation of a lower limb that requires one or more of the listed appliances or services. As such, requiring that the patient has had such an amputation and requires one or more of the listed appliances/services is appropriate for utilization review for the prior authorization of these procedures. The specification of timing for application of the temporary prosthesis and non-weight bearing rigid dressing is important, because eventually the residual limb will be ready for a permanent

or definitive prosthesis and the temporary prosthesis or rigid dressing will no longer be appropriate. Subsections (a)(2)(I)1. and 3., represent appliances designed to be applied before the wound has completely healed; they are not designed as definitive or permanent prostheses. Subsection (a)(2)(I)2., represents only a cast change and realignment of the temporary prosthesis and therefore is considered a service.

13. [Subsection (a)(2)(J)] Establish that initial prostheses shall be authorized when the patient has had a lower limb amputation that requires a temporary prosthesis, and when the prosthesis is applied after the wound has healed, but the residual limb has not reached its final shape. This subsection also specifies an initial prosthesis may be authorized when it is used after the original amputation or after a residual limb revision(s). This type of prosthesis is designed, developed, and marketed for patients with an amputation of a lower limb that requires a temporary prosthesis to permit some lower limb function. As such, requiring that the patient has had such an amputation and requires a temporary prosthesis is appropriate for utilization review for the prior authorization of these prostheses. The specification of timing for application of the temporary prosthesis is important, because eventually the residual limb will be ready for a permanent or definitive prosthesis, and the temporary prosthesis will not be appropriate.
14. [Subsection (a)(2)(K)] Establish that preparatory prostheses - below knee shall be authorized when the patient has had a below-the-knee amputation and requires a temporary prosthesis to permit some ambulation or other functional activities in preparation for the fitting of a definitive prosthesis, and when the prosthesis is applied after the wound has healed, but the residual limb has not reached its final shape. This subsection also specifies a preparatory prosthesis may be authorized when it is used after the original amputation or after a residual limb revision(s). This type of prosthesis is designed, developed, and marketed for patients with an amputation of a lower limb that requires a temporary prosthesis to permit some ambulation or other functional activities. As such, requiring that the patient has had such an amputation and requires a temporary prosthesis is appropriate for utilization review for the prior authorization of these prostheses. The specification of timing for application of the preparatory prosthesis is important, because eventually the residual limb will be ready for a permanent or definitive prosthesis, and the preparatory prosthesis will not be appropriate.
15. [Subsection (a)(2)(L)] Establish that preparatory prostheses - above knee shall be authorized when the patient has had an above-the-knee amputation and requires a temporary prosthesis to permit some ambulation or other functional activities in preparation for the fitting of a definitive prosthesis, and when the prosthesis is applied after the wound has healed, but the residual limb has not reached its final shape. This subsection also specifies a preparatory prosthesis may be authorized when it is used after the original amputation or after a residual limb revision(s). This type of prosthesis is designed, developed, and marketed for patients with an amputation of a lower limb that requires a temporary prosthesis to permit some ambulation or other functional activities. As such, requiring that the patient has had such an amputation and requires a temporary

prosthesis is appropriate for utilization review for the prior authorization of these prostheses. The specification of timing for application of the preparatory prosthesis is important, because eventually the residual limb will be ready for a permanent or definitive prosthesis, and the preparatory prosthesis will not be appropriate.

16. [Subsection (a)(2)(M)] Establish that additions to lower limb prostheses include all of the appliances listed in subsections (a)(2)(M)1.a. through i., and shall be authorized when all of the criteria listed in subsections (a)(2)(M)2.a. through c., are met.

    *These requirements for the prior authorization of additions are consistent throughout this proposed regulatory action as they pertain to other prostheses. Specifically, the patient's medical condition must require the specific function for which the addition(s) was designed. The addition(s) must be necessary to improve the functionality of the base appliance, without which the patient's medical need(s) would not be met. If the patient's medical need(s) is not met with the addition(s), the purchase would serve no useful purpose and represent an unnecessary expenditure under Medi-Cal. The patient must have an existing or authorized base appliance compatible with the addition(s). Incompatibility between the base appliance and the addition(s) would result in the lower limb prostheses being non-functional.

    These requirements for additions are necessary to determine the addition(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.

17. [Subsection (a)(2)(N)] Establish that replacements - feet-ankle units shall be authorized when both of the criteria listed in subsections (a)(2)(N)1. and 2., are met. The replacement cost(s) must be less than the cost(s) of purchasing a new appliance [(a)(2)(N)1.]. This will preclude the prior authorization for replacement of appliances when the replacement cost is equal to or greater than the cost of purchasing a new prosthesis. This restriction promotes cost effectiveness under Medi-Cal by prohibiting the unnecessary replacement of appliances when it would be the same cost or less costly to purchase a new prosthesis. The patient must have an existing or authorized lower limb prosthesis compatible with the requested replacement(s) [(a)(2)(N)2.]. If the foot-ankle unit is not compatible with the lower limb prosthesis, the result would be a non-functioning prosthesis. These requirements for replacements are necessary to determine the replacement(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.
18. [Subsection (b)] Establish that subsections (b)(1) through (10) make up a group of appliances called "upper limb prostheses."
19. [Subsection (b)(1)] Establish that partial hand prostheses shall be authorized when the patient has had an amputation of part or all of the hand and requires a definitive prosthesis to permit functional use of the upper extremity. This type of prosthesis is designed, developed, and marketed for patients with an amputation of part or all of the hand requiring a prosthesis for functional use of the upper extremity. As such, requiring that the patient has had such an amputation and

requires a definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.

20. [Subsection (b)(2)] Establish that wrist disarticulation prostheses shall be authorized when the patient has had an amputation through or near the wrist and requires an exoskeletal definitive prosthesis to permit functional use of the upper extremity. This type of prosthesis is designed, developed, and marketed for patients with an amputation through or near the wrist requiring a prosthesis for functional use of the upper extremity. As such, requiring that the patient has had such an amputation and requires an exoskeletal definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
21. [Subsection (b)(3)] Establish that elbow prostheses shall be authorized when the patient has had an amputation near the elbow and requires an exoskeletal definitive prosthesis to permit functional use of the upper extremity. This type of prosthesis is designed, developed, and marketed for patients with an amputation near the elbow requiring a prosthesis for functional use of the upper extremity. As such, requiring that the patient has had such an amputation and requires an exoskeletal definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
22. [Subsection (b)(4)] Establish that shoulder prostheses shall be authorized when the patient has had an amputation through or near the shoulder and requires an exoskeletal definitive prosthesis to permit functional use of the upper extremity. This type of prosthesis is designed, developed, and marketed for patients with an amputation through or near the shoulder requiring a prosthesis for functional use of the upper extremity. As such, requiring that the patient has had such an amputation and requires an exoskeletal definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
23. [Subsection (b)(5)] Establish that interscapular thoracic prostheses shall be authorized when the patient has had an amputation with removal of both the shoulder joint and the scapula and requires an exoskeletal definitive prosthesis to permit functional use of the upper extremity. This type of prosthesis is designed, developed, and marketed for patients with an amputation with removal of both the shoulder joint and the scapula requiring a prosthesis for functional use of the upper extremity. As such, requiring that the patient has had such an amputation and requires an exoskeletal definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
24. [Subsection (b)(6)] Establish that immediate and early post-surgical procedures shall be authorized when the patient has had an upper limb amputation and requires one or more of the appliances/services listed in subsections (b)(6)(A) through (C). A temporary prosthesis shall be authorized when it is applied soon after amputation, before the wound has completely healed, to permit some lower extremity function [(b)(6)(A)]. This subsection also specifies a temporary prosthesis may be authorized when it is used after the original amputation or after a residual limb revision(s). An additional cast change(s) and realignment(s) of the temporary prosthesis specified in subsection (b)(6)(A) shall be authorized when the patient has an existing or authorized temporary prosthesis that requires these services [(b)(6)(B)]. A temporary application of a non-weight bearing rigid

dressing shall be authorized when it is applied soon after amputation, before the wound has completely healed, and when there is no expectation of use of a prosthesis until the wound has completely healed [(b)(6)(C)]. This subsection also specifies a rigid dressing may be authorized when it is used after the original amputation or after a residual limb revision(s). Immediate and early post-surgical procedures are designed, developed, and marketed for patients with an amputation of an upper limb, who require one or more of the listed appliances/services. As such, requiring that the patient has had such an amputation and requires one of the listed appliances or services is appropriate for utilization review for the prior authorization of these procedures. The specification of timing for application of the temporary prosthesis and non-weight bearing rigid dressing is important, because eventually the residual limb will be ready for a permanent or definitive prosthesis, and the temporary prosthesis or rigid dressing will no longer be appropriate. Subsections (b)(6)(A) and (C) represent appliances designed to be applied before the wound has completely healed; they are not designed as definitive or permanent prostheses. Subsection (b)(6)(B) represents only a cast change and realignment of the temporary prosthesis and therefore is considered a service.

25. [Subsection (b)(7)] Establish that endoskeletal - elbow or shoulder area prostheses shall be authorized when the patient has had an upper extremity amputation and requires a definitive prosthesis to permit functional use of the upper extremity. This type of prosthesis is designed, developed, and marketed for patients with an upper limb amputation requiring a prosthesis for functional use of the upper extremity. As such, requiring that the patient has had such an amputation that requires a definitive prosthesis is appropriate for utilization review for the prior authorization of these prostheses.
26. [Subsection (b)(8)] Establish that endoskeletal interscapular thoracic prostheses shall be authorized when the patient has had an upper extremity amputation and requires a temporary or preparatory prosthesis to permit some upper extremity function in preparation for the fitting of a definitive prosthesis; and for when the prosthesis is applied after the wound has healed, but the residual limb has not reached its final shape. This subsection also specifies an endoskeletal interscapular thoracic prosthesis may be authorized when it is used after the original amputation or after a residual limb revision(s). This type of prosthesis is designed, developed, and marketed for patients with an upper extremity amputation requiring a prosthesis to permit some upper extremity function. As such, requiring that the patient has had such an amputation and requires a temporary or preparatory prosthesis is appropriate for utilization review for the prior authorization of these prostheses. The specification of timing for application of the temporary or preparatory prosthesis is important, because eventually the residual limb will be ready for a permanent or definitive prosthesis, and the temporary prosthesis will not be appropriate.
27. [Subsection (b)(9)] Establish that additions to upper limb prostheses shall be authorized when all of the criteria listed in subsections (b)(9)(A) through (C) are met. These requirements for the prior authorization of additions are consistent throughout this proposed regulatory action (see number 16* above). These

requirements for additions are necessary to determine the addition(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.

28. [Subsection (b)(10)] Establish that replacements for upper limb prostheses shall be authorized when both of the criteria listed in subsections (b)(10)(A) and (B) are met. The replacement cost(s) must be less than the cost(s) of purchasing a new prosthesis [(b)(10)(A)]. This will preclude the prior authorization for replacement of appliances when the replacement cost is equal to or greater than the cost of purchasing a new prosthesis. This restriction promotes cost effectiveness under Medi-Cal by prohibiting the unnecessary replacement of appliances when it would be the same cost or less costly to purchase a new prosthesis. The patient must have an existing or authorized upper limb prosthesis compatible with the replacement(s) [(b)(10)(B)]. If the replacement is not compatible with the upper limb prosthesis, the result would be a non-functioning prosthesis. These requirements for replacements are necessary to determine the replacement(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.
29. [Subsection (c)] Establish that subsections (c)(1) through (3) make up a group of appliances called “terminal devices.”
30. [Subsection (c)(1)] Establish that hooks, which include both the base appliance and any required addition(s) or attachment(s) shall be authorized when one or both of the criteria specified in subsections (c)(1)(A) and (B) are met. For the base appliance, both of the criteria specified in subsections (c)(1)(A)1. and 2., must be met. The patient must require a terminal device to permit functional use of the upper extremity [(c)(1)(A)1.] and the patient must have an existing or authorized upper extremity prosthesis compatible with the requested terminal device [(c)(1)(A)2.]. If the patient had no need for the terminal device, there would be no reason to authorize the terminal device. If the patient’s existing or authorized upper extremity prosthesis is not compatible with the terminal device, the result would be a non-functioning prosthesis. For the addition(s) or attachment(s), all of the criteria specified in subsections (c)(1)(B)1. through 3., must be met. These requirements for the prior authorization of additions or attachments are consistent throughout this proposed regulatory action (see number 16* above). These requirements for addition(s) or attachments(s) are necessary to determine the addition(s) or attachment(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.
31. [Subsection (c)(2)] Establish that hands, which includes both the base appliance or device and any required addition(s) or attachment(s) shall be authorized when one or both of the criteria specified in subsections (c)(2)(A) and (B) is met. For the base appliance or device, both of the criteria specified in subsections (c)(2)(A)1. and 2., must be met. The patient must require a terminal device to permit functional use of the upper extremity [(c)(2)(A)1.] and the patient must have an existing or authorized upper extremity prosthesis compatible with the requested terminal device [(c)(2)(A)2.]. If the patient has no need for the terminal device, there would be no reason to authorize the terminal device. If the patient’s existing or authorized upper extremity prosthesis is not compatible with the

terminal device, the result would be a non-functioning prosthesis. For the addition(s) or attachment(s) all of the criteria specified in subsections (c)(2)(B)1. through 3., must be met. These requirements for the prior authorization of additions or attachments are consistent throughout this proposed regulatory action (see number 16* above). These requirements for addition(s) or attachments(s) are necessary to determine the addition(s) or attachment(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.

32. [Subsection (c)(3)] Establish that hand restoration shall include casts, shading and measurements and be authorized when one or both of the criteria specified in subsections (c)(3)(A) and (B) are met. For the partial hand prosthesis, both of the criteria specified in subsections (c)(3)(A)1. and 2., must be met. The patient must require a partial hand prosthesis to permit functional use of the upper extremity [(c)(3)(A)1.] and the patient must have an existing or authorized upper extremity prosthesis compatible with the requested partial hand prosthesis [(c)(3)(A)2.]. If the patient had no need for the partial hand prosthesis, there would be no reason to authorize the partial hand prosthesis. If the patient's existing or authorized upper extremity prosthesis is not compatible with the partial hand prosthesis, the result would be a non-functioning prosthesis. For the replacement glove(s), both of the criteria specified in subsections (c)(3)(B)1. and 2., must be met. The patient must require a replacement glove(s) for a hand prosthesis [(c)(3)(B)1.] and the patient must have an existing or authorized hand prosthesis compatible with the requested replacement glove(s) [(c)(3)(B)2.]. If the patient had no need for the replacement glove(s) and/or the patient's existing or authorized hand prosthesis was not compatible with the replacement glove(s), there would be no reason to authorize the replacement glove(s). These requirements for replacements are necessary to determine the replacement(s) is medically necessary for the patient and represents an appropriate expenditure under Medi-Cal.
33. [Subsection (d)] Establish that subsections (d)(1) through (4) make up a group of appliances called "external power."
34. [Subsection (d)(1)] Establish that base devices shall be authorized when both of the criteria specified in subsections (d)(1)(A) and (B) are met. The patient must require an upper extremity prosthesis with one or more electrically powered functional parts or electronic circuitry activated by the patient to allow effective movement of the upper extremity in the performance of ADLs and IADLs [(d)(1)(A)] and the patient must not be able to otherwise effectively use a manually operated prosthesis [(d)(1)(B)]. These specialized, electrically powered prostheses are designed, developed, and marketed for patients who cannot effectively use a manual prosthesis to allow effective movement of the upper extremity. As such, requiring that the patient has such a condition that requires an upper extremity prosthesis, and the patient is unable to use a manually operated prosthesis, is appropriate for utilization review for the prior authorization of these prostheses. The use of ADLs and IADLs as the benchmark is consistent with the discussion under Section 51315(c)(2).

35. [Subsection (d)(2)] Establish that terminal devices shall be authorized when all of the criteria specified in subsections (d)(2)(A) through (C) are met. The patient must require a terminal device with one or more electrically powered functional parts or electronic circuitry activated by the patient to allow effective movement of the upper extremity in the performance of ADLs and IADLs [(d)(2)(A)]; the patient must not be able to otherwise effectively use a manually operated prosthesis [(d)(2)(B)]; and the patient must have an existing or authorized upper extremity prosthesis compatible with the terminal device [(d)(2)(C)]. These specialized, electrically powered terminal devices are designed, developed, and marketed for patients who cannot effectively use a manual prosthesis to allow effective movement of the upper extremity. As such, requiring that the patient has a condition that requires a terminal device, has a compatible upper extremity prosthesis and is unable to use a manually operated prosthesis is appropriate for utilization review for the prior authorization of these prostheses. Incompatibility with an existing or authorized upper extremity prosthesis would make use of the terminal device impossible. The use of ADLs and IADLs as the benchmark is consistent with the discussion under Section 51315(c)(2).
36. [Subsection (d)(3)] Establish that elbow attachments shall be authorized when all of the criteria specified in subsections (d)(3)(A) through (C) are met. The patient must require an elbow attachment with one or more electrically powered functional parts or electronic circuitry activated by the patient to allow effective movement of the upper extremity in the performance of ADLs and IADLs [(d)(3)(A)]; the patient must not be able to otherwise effectively use a manually operated prosthesis [(d)(3)(B)]; and the patient must have an existing or authorized upper extremity prosthesis compatible with the elbow attachment [(d)(3)(C)]. These specialized, electrically powered elbow attachments are designed, developed, and marketed for patients who cannot effectively use a manual prosthesis to allow effective movement of the upper extremity. As such, requiring that the patient has such a medical condition that requires an elbow prosthesis, has a compatible upper extremity prosthesis, and is unable to use a manually operated prosthesis, is appropriate for utilization review for the prior authorization of these prostheses. Incompatibility with an existing or authorized upper extremity prosthesis would make use of the terminal device impossible. The use of ADLs and IADLs as the benchmark is consistent with the discussion under Section 51315(c)(2).
37. [Subsection (d)(4)] Establish that control modules and battery components shall be authorized when the patient has an existing or authorized upper extremity electrically powered prosthesis that requires a control module or battery component for functional use of the prosthesis. This requirement is appropriate because compatibility is essential for effective operation of the prosthesis.
38. [Subsection (e)] Establish that breast prostheses shall be authorized when the patient requires a prosthesis, component, or attachment to replace a breast(s) after surgical removal, to support the surgical recovery, or to hold the prosthesis in place. Breast prostheses are not considered to be solely for cosmetic restoration [Section 51315(d)(2)] and therefore may be authorized under Medi-Cal when this criterion is met.

39. [Subsection (f)] Establish that subsections (f)(1) and (2) make up a group of appliances called "general items."
40. [Subsection (f)(1)] Establish that prosthetic socks shall be authorized when both of the criteria specified in subsections (f)(1)(A) and (B) are met. The patient must require one or more of the appliances listed in subsections (f)(1)(A)1. through 4., and the patient must have an authorized or existing lower extremity prosthesis compatible with the prosthetic sheath, sock, or shrinker [(f)(1)(B)]. These appliances are designed, developed, and marketed for patients who use prosthesis and require one or more of the general items listed for the specific purpose stated. As such, requiring that the patient needs one or more of these items and that the patient's authorized or existing prosthesis is compatible with the item, is appropriate for utilization review for these general items.
41. [Subsection (f)(2)] Establish that repairs for prosthetic appliances include repairs, maintenance, replacements, and associated labor and shall be authorized when the criteria specified in subsections (f)(2)(A) through (C) are met. The patient must have an existing prosthesis that requires repair, maintenance, or replacement [(f)(2)(A)]. The repair, maintenance, or replacement cost(s) (including associated labor) must be less than the cost(s) of purchasing a new appliance [(f)(2)(B)]. This restriction promotes cost effectiveness under Medi-Cal by prohibiting the unnecessary repair, maintenance, or replacement related to appliances when it would be the same cost or less costly to purchase a new appliance. In addition, the request or claim, when the appliance or service does not require prior authorization, must include a list of the components to be repaired or replaced and a statement explaining the necessity for the repair or replacement [(f)(2)(C)]. This requirement supports the Department's mandate to provide utilization review and to preclude unnecessary costs to Medi-Cal.
42. [Subsection (g)] Establish that miscellaneous prosthetic appliances shall be authorized when the patient has had an amputation or removal of a body part and requires one or more of the appliances or devices listed in subsections (g)(1) through (6), appropriate to the requested procedure code. Subsection (g)(1) specifies those prosthetic appliances and services not functionally equivalent to, and do not meet the descriptor for, existing prosthetic appliances and services procedure codes, shall be authorized under the "miscellaneous prosthetic appliances" category. These appliances are designed, developed, and marketed for patients who have had an amputation or removal of a body part and require one or more of the appliances listed for the specific purpose stated. As such, requiring that the patient has had an amputation or removal of a body part that requires one or more of these appliances is appropriate for utilization review for the prior authorization of these appliances.

DOCUMENTS RELIED ON

The following were relied upon in the development of this regulatory proposal:

- Illustrated Guide to Orthotics and Prosthetics 2012, published by The American Orthotic and Prosthetic Association.

- Healthcare Common Procedure Coding System (2012 HCPCS Level II Professional Edition), published by The American Medical Association.

STATEMENTS OF DETERMINATION

A. ALTERNATIVES CONSIDERED

The Department has determined 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 this action is proposed, would be as effective and less burdensome to affected private persons and equally effective in implementing the statutory policy or other provisions of the 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.

B. LOCAL MANDATE DETERMINATION

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.

C. ECONOMIC IMPACT ANALYSIS/ASSESSMENT

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.

The Department has determined that the proposed regulations would not significantly affect the following:

1. The creation or elimination of jobs in California.
2. The creation of new businesses or the elimination of existing businesses within California.
3. The expansion of businesses doing business within 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 Regulations

Also, 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.

D. 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.

E. HOUSING COSTS DETERMINATION

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