Commenter Name, Title, Organization and Date of Comment(s)

1. Bryce W.A. Docherty, Executive Director, Legislative & regulatory advocate California Orthotic & Prosthetic Association (COPA) (October 23, 2014)

Comment

We submitted written comments. I want to orally walk through those comments.

Response

Please refer to FSOR Addendum 1, Commenter #2, pages 6-19, for responses.

Comment

1. First, Section 51315 speaks to the amount, scope, duration, limitation and prior authorization of benefits for orthotic and prosthetic services. It specifically amends subsection (a)(1) which establishes that licensed pharmacists and pharmacies may furnish O&P appliances and services pursuant to an added section, subsection (a)(3). Added subsection (a)(3) references only appliances and services listed in the Medi-Cal Provider Manual pursuant to Welfare and Institutions Code (W&I) section 14105.21. Our current understanding is that the current list of double-asterisked codes in the Medi-Cal Provider Manual established by the Department for this specific purpose only includes the following codes. There are 12 codes. L0120, L1902, L3908, L8300, L8310, L8320, L8330, L8000, L8001, L8002, L8010 and L8015.

Response

See responses below.

Comment

1a. Our questions with this section are as follows. Are these the same codes that will still apply to the subsection being added under (a)(3)?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #3a. for response.

Comment

1b. Two, does the Department plan on changing and or expanding the list of codes authorized by the added subsection (a)(3)?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #3b. for response.

Comment

1c. And, three, what statutory authority does the Department have to explicitly include a “licensed” pharmacist under amended subsection (a)(1)?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #3c. for response.

Comment

1d. Our concerns are that certified pharmacies would be authorized to furnish customized orthotic and prosthetic appliances. Notwithstanding physicians and surgeons or podiatrists, only certified orthotists and prosthetists have the unique education and training to appropriately fit, fabricate and furnish these appliances. Pharmacies should only be able to furnish the existing aforementioned codes currently authorized by DHCS and specifically identified in the Medi-Cal Provider Manual.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #3d. for response.

Comment

1e. Furthermore, COPA believes by expanding the existing law to include a licensed pharmacist could potentially constitute an underground regulation. W&I section 14105.21 only references a certified pharmacy. COPA suggests the Department seek legislation to provide the enabling statutory authority to expand this section to include a licensed pharmacist. Any such legislation should also include a requirement that a licensed pharmacist also be certified in orthotics and prosthetics by either the Board of Orthotic Certification or the American Board of Certification in Orthotics and Prosthetics. The same requirement applies to orthotists and prosthetists as a condition of participating in the Medi- Cal program pursuant to W&I section 14132.63.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #3e. for response.

Comment

2. An additional subsection (b) in that same section includes language regarding record keeping and prior authorization requests. Our questions are as follows.

Response

See responses below.

Comment

2a. What providers, for example, licensed physician, podiatrists and dentists or nonphysician medical practitioners, are subject to the proposed medical record, “clinical notes” requirement documenting medical necessity?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #4a. for response.

Comment

2b. To what extent does the record keeping requirement apply to O&P practitioners?

Response

Please refer to FSOR Addendum 1, Commenter #2, Comment #4b. for response.

Comment

2c. Notwithstanding amended subsection (c), what specific documentation of medical necessity shall accompany a prior authorization request?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #4c. for response.

Comment

2d. Our concern as it pertains to this section and the aforementioned questions are COPA needs to specifically articulate and advise our

membership on how best to meet these record keeping requirements. In general, the prior authorization process can be fickle. We hope to minimize the interruptions in providing O&P appliances and services to Medi-Cal beneficiaries by being abundantly clear on what specific documentation is necessary to expedite the prior authorization process articulated in this proposed rulemaking.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #4d. for response.

Comment

3. Added subsection (c)(2) and (c)(3) applies to documentation necessary to determine prior authorization and medical necessity necessary for O&P appliances and services. Our questions under this added subsection are as follows.

Response

See responses below.

Comment

3a. First, who will be determining whether or not the appliance or service is essential to performing activities of daily living or instrumental activities of daily living?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #5a. for response.

Comment

3b. Two, under added subsection (c)(3), who will be determining whether or not the appliance or service is consistent with the patient's previous abilities and limitations, as they relate to activities of daily living, prior to the onset of disability or injury, or as appropriate to the patient's chronological and developmental age?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #5b. for response.

Comment

3c. Under both subsections (c)(2) and (c)(3), what qualifications would the presumed individual have to make these sorts of determinations? For example, how would these determinations be made and what test would be subject to that determination?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #5c. for response.

Comment

3d. These determinations of active daily living and previous ability limitations can be highly subjective. Personnel relied upon by the Department and the qualifications of these personnel and the quantitative analysis relied upon by these personnel is tantamount to us in terms of ensuring adequate and timely access to care for Medi-Cal beneficiaries.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #5d. for response.

Comment

3e. Furthermore, the Medi-Cal program may need to incur significant additional costs for "testing and evaluation" by a physical therapist, occupational therapist and/or physician. COPA is concerned that subjective determinations on active daily living would not only delay the prior authorization process and delay O&P care for Medi-Cal beneficiaries but also negatively impact the reimbursement time line for providers that are already struggling with a challenging Medi-Cal reimbursement rate for these O&P appliances and services.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #5e. for response.

Comment

4. Another added subsection, (d)(4), addresses denials of prior authorization of O&P appliances and services when the appliance or service is a benefit that is included as part of the acute inpatient hospital stay and the date of service occurs during that stay. Our questions with this subsection are as follows.

Response

See responses below.

Comment

4a. How will the O&P practitioner know or be able to determine if such an appliance or service is included in the hospital contract?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #6a. for response.

Comment

4b. Secondly, how and where is the "acute inpatient hospital stay" defined? For example, would prior authorization not be granted under this subsection if an appliance or service is also provided in the skilled nursing facility, long-term care facility or acute rehab facility?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #6b. for response.

Comment

4c. Our concerns with this section are that existing Medi-Cal provisions in this regard are already confusing for many O&P practitioners and hospital facilities. O&P practitioners provide a bevy of appliances and services in many different facility settings. This specific provision may, in fact, create a detrimental delay in the provision of O&P care.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #6c. for response.

Comment

5. Another added subsection, subsection (d)(6) addresses denial or prior authorization for the purchase or replacement of an O&P appliance when the patient's existing appliance can be repaired at a cost less than the cost of actually purchasing a new appliance, unless the existing appliance does not meet the patient's medical need or needs as documented by a licensed physician, licensed podiatrist, licensed dentist or licensed nonphysician medical practitioner.

Response

See responses below.

Comment

5a. Our question with this subsection is: How will this determination be made? For example, will the O&P practitioner be required to provide a repair estimate or will the O&P appliance manufacturer or vendor be required to provide documented manufactured suggested retail price of a

specific appliance? In the event an appliance must be returned to the manufacturer of a subcomponent for the repair estimate, how does the O&P practitioner get paid and/or reimbursed for these costs? For example, some appliances can only be repaired by the manufacturer. For example, these would include hydraulic units in a prosthetic knee, some components of prosthetic feet and hands. There are an increasing complex array of nonfield serviceable appliances and systems in the marketplace. In order to obtain a repair estimate for these appliances, the O&P practitioner must remove the item, ship it to the manufacturer, pay the manufacturer to provide the repair estimate and return shipping if not repaired. These repair estimates from the manufacturer are only valid for a limited time, often less than the treatment authorization request processing requirement. Whom does the Department assume incurs these costs?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #7a. for response.

Comment

5b. Our concern with this section is, of course, we strongly believe that any additional unnecessary costs or labor for O&P practitioners to participate in the Medi-Cal program will force them to the leave the program.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #7b. for response.

Comment

6. Added subsection (d)(7) addresses denials of prior authorization for fitting, measuring, training, or delivery of an O&P appliance separate from the authorization of the appliance itself.

Response

See responses below.

Comment

6a. Our question here is, quite frankly, this subsection makes little to no sense to us and requires further clarification. Does this mean, for example, that the O&P practitioner will get reimbursed separately for the appliance and the fitting, measuring, training, and delivery; or does this subsection mean there is no pathway or methodology for an O&P practitioner to get prior authorization for fitting, measuring, training, and delivery of an appliance? This will be especially acute with the new, “split codes.” These are identical appliances that get billed using different codes if the appliance is “off the shelf” or custom fitted. For example, if an “off the shelf” appliance is furnished to a beneficiary by an entity that cannot custom fit the appliance, how will that be resolved by the Department? Coincidentally, O&P practitioners by and large do not adjust or repair appliances furnished by another provider, primarily due to product liability risks.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #8a. for response.

Comment

6b. Our concern with this subsection, again, is that with making sure the Medi-Cal program functions properly to address the O&P needs of its beneficiaries. To that end, prior authorization for appliances and services must be covered. An O&P appliance that is ill-fitted, measured incorrectly, or if the patient is not properly trained on how to use the appliance, can have a devastating impact on their ability to heal properly and/or restore the active daily living they sorely deserve.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #8b. for response.

Comment

7. I want to do just a brief commentary on Medi-Cal reimbursement for O&P appliances in general. I understand this is not under the purview of the regulatory rulemaking.

Amended subsection (e) applies to reimbursement conditions for O&P appliances and services. The primary condition is that reimbursement shall not exceed 80 percent of the lowest maximum allowance for California established by Medicare for the same or similar services.

COPA has relied upon data provided by the Department over the years illustrating that the reimbursement for the category of O&P appliances and services has decreased at least $20 million, well in excess of 50 percent, over the past ten years with at least 520,000 fewer appliances reaching Medi-Cal beneficiaries. Unfortunately, the human cost of this ongoing trend can be devastating.

COPA specifically proposes paying the O&P appliances and services reimbursement at 80 percent of the applicable Medicare allowable in effect on the date of service, which is still consistent with existing law stating these rates cannot exceed that amount. New codes that are added by Medicare and eventually adopted by Medi-Cal are initially pegged at 80 percent of the maximum allowable and then those rates diminish over time. In fact, some current O&P codes are barely reimbursed at 15 percent of the Medicare allowable.

The prosthetic and orthotic category has not received an increase in reimbursement in over 20 years; while the cost of materials, labor and overhead needed to produce the products have skyrocketed. With reimbursement rates for many of these services pegged at less than the cost of the production factors, Medi-Cal is no longer accepted by an increasing number of O&P practitioners throughout California. This can be

evidenced by the lack of new provider applications for this category. Therefore, Medi-Cal beneficiaries may be forced to recycle junk components or navigate the streets on crutches or carts and have limited or no local access to appropriate levels of care that increases needed access to other medical services.

Without a definitive and consistent reimbursement methodology rate for these appliances in the Medi-Cal program, vulnerable patients may continue to suffer from substantial and lasting disabilities. These patients, many of whom are amputees, will struggle to achieve proper use and maintenance of worn out or defective O&P devises, increasing the likelihood of chronic disability or injury.

Therefore, our overall objective is to ensure that the vulnerable and disabled Medi-Cal population will not be forced to continue using old and inferior appliances that fail to completely restore their function. Our secondary objective is to also ensure greater access to care for these medically compromised patients who are in jeopardy of not completely healing properly or recovering from surgery and, therefore, may eventually require more costly Medi-Cal services.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #9. for response.

Commenter Name, Title, Organization and Date of Comment(s)

2. Jeff Collins, CPA, President, COPA, Executive Committee, AOPA, Owner/Operator of Cascade Orthopedic Supply (October 23, 2014)

Comment

1. Specifically, we'd like to know which providers are qualified to provide which devices that you so clearly defined in the proposed regulations. Pharmacists are called out in these regulations to provide some of the devices, and we would like to know where are those lines drawn? Which providers are qualified to provide which devices? O&P devices are amazingly complex and require professional review and provision by experts in the field, and the O&P industry that I'm proud to represent today has a long history of providing these devices and the clinical care to help beneficiaries achieve the best outcomes with those devices.

Response

Please refer to FSOR, Addendum 1, Commenter #1, Comment #4. for response.

Section 51315 describes which providers may prescribe and/or furnish O&P devices.

Comment

2. So as I look at these proposed regulations, I want to ensure that beneficiaries continue to have access to the best providers of that care going forward. I'd like to see more specificity on the clinical notes that support medical necessity.

Response

Please refer to FSOR, Addendum 1, Commenter #3, Comment #7. for response.

Comment

3. At a national level, AOPA seeks to understand where our clinicians' notes fall with respect to their standing supporting medical necessity, and we'll have some experts talk about that today.

Response

This regulatory action, Section 51315(b), requires that a provider who prescribes and/or furnishes O&P appliances and services must document and maintain records that justify medical necessity for the requested appliances and services. Depending upon the provider type, medical necessity documentation may vary; however, since it is the O&P provider who submits the TAR for authorization of the requested appliances and services, the provider must maintain records, which may have been obtained through other health care providers. These records must justify medical necessity for authorization of the requested appliances and services.

Comment

4. We'd like to know who will assess the patients' ADLs, activities of daily living, both pre and post provision of the device. Who is going to do that? That's of great interest to us.

Response

The assessment of ADLs is part of the total assessment of the patient to determine his/her medical/equipment needs. This assessment can be done by any health care professional within his/her scope of practice. Section 51315(a)(1) specifies requirements for the prescription and furnishing of O&P appliances and services.

Comment

5. On the business side of the regs, we'd like to understand the time line in which the Department will respond to the prior authorization requests. We want to ensure the beneficiaries have quick access to the clinical care that they need to continue fulfilling their daily life and getting back to that standard of living that they had prior to a disability or an injury.

Response

The Department appreciates this comment; however, prior authorization timelines are outside the scope of this regulatory action.

Comment

6. Also on the business side, we'd like to understand a little bit more about the reimbursement rates. You suggested an 80 percent of Medicare rate. This language may subject some providers to compliance issues with federal contracts they have in place today. So I want to ensure that we're thinking along those lines.

   And, also to support what Bryce had talked about earlier in that these rates that are currently in place for Medi-Cal providers already put providers in a precarious position to provide these services and devices at best at a break-even point and in most cases at a loss.

Response

The Department appreciates this comment; however, provisions related to reimbursement have remained unchanged and are outside the scope of this regulatory action.

Commenter Name, Title, Organization and Date of Comment(s)

3. Brandon Dale, Hanger Clinic & COPA (October 23, 2014)

Comment

The backdrop of the comments that are prepared in the letter dated October 2, 2014 are based on federal law statute according to the Department of Health and Human Services Center for Medicare and Medicaid Services, specifically the DMEPOS standards, DMEPOS, meaning Durable Medical Equipment Prosthetic and Orthotic Supplies.

Response

See responses below.

Comment

1. In general, our first comments are for the amended Section 51161, and we note four specific definitions that stray from current Medicare definitions, so we ask those four examples be considered for correction to mirror Medicare definitions.

Response

Please refer to FSOR, Addendum 1, Commenter #3, Comments 1-5 for response.

Comment

2. We go on in the letter to comment on added Section 51315. I'd like to call specific attention to our second and third comment under these sections, the first of which would be under 51315, subsection (a), subsection (3), orthotic and prosthetic appliances and services listed in the Medi-Cal Provider Manual pursuant to W&I section 14105.21 must be furnished and billed by pharmacists or pharmacies. Medicare is specifically indicated that for some devices, specifically devices that are not considered to be off-the-shelf, be provided by a certified orthotist, is contradictory to this edition.

   I would also like to call attention to the DMEPOS quality standards as published by the Department of Health and Human Services Appendix (c) that reads in part: Individuals supplying the items set out in this exhibit must possess certification and/or licensing in specialized education, training, experience and fitting, and this is in reference to custom fabricated, custom fit orthoses, prosthetic devices, therapeutic shoes and inserts and their accessories and supplies, custom and facial prostheses, and others. I will also note in this same quality standards document that off-the-shelf products are defined, that they do not require expertise in fitting. So to be clear, the objection is not allowing pharmacists or pharmacies to fit or distribute off-the-shelf items, but rather custom fit and custom made orthotic and prosthetic devices. Further, in the same DMEPOS quality standards, Medicare, CMS, rather, recognizes ten accrediting around DMEPOS providers, one of which of these accrediting organizations is the National Association of the Board of Pharmacies, otherwise known as NABP. As a part of their accreditation they note that they limit pharmacists from providing specific items. The NABP does not provide accreditation for DMEPOS quality standards in Appendix (b) of the DMEPOS quality standards, custom fabricated and custom fit orthoses and prosthetic devices and custom made semantic ocular and facial prostheses. So it's important to note that the pharmacists governing board limits their scope in DMEPOS quality standards as well.

Response

Please refer to FSOR, Addendum 1, Commenter #3, Comment #6. for response (which references Commenter #1, Comment #4., of Addendum 1).

Comment

3. My last comment, staying consistent with Section 51315, subset (b), speaks to a written prescription signed by a licensed physician, a licensed podiatrist, a licensed dentist or a licensed nonphysician medical practitioner and clinical notes that document the medical necessity of

the appliance or service shall be maintained by the provider in the patient's medical records pursuant to Section 51476. It should be noted that clinical notes can be any part of the official medical record and may include an orthotist's notes. We suggest revising this language to include the definition of clinical notes which clearly identifies and includes all medical professional's records.

Response

Please refer to FSOR, Addendum 1, Commenter #3, Comment #7. for response.

Comment

4. In closing, I would like to come back to something I said in the beginning of my comments, and what was that the backdrop of our comments from Hanger are surrounding federal law, federal statute through Health and Human Services and we believe that the State is venturing away from federal law, specifically in health care. And as we're talking today regarding orthotics and prosthetics, can become dangerous for the patients that are covered by these programs.

Response

Please refer to FSOR, Addendum 1, Commenter #3, Comments 1-7 for response.

Commenter Name, Title, Organization and Date of Comment(s)

4. Harry Brandt, Certified Orthotist, Certified Investigator Inspector (October 23, 2014)

Comment

1. I would caution strongly against pharmacy or anybody outside of that negotiated rule making process having access to custom fitted or custom made orthotic and prosthetic devices, the off-the-shelf, is something that again is not a bone of contention.

Response

Please refer to FSOR, Addendum 1, Commenter #1, Comment #4. for response.

Commenter Name, Title, Organization and Date of Comment(s)

5. Matthew Garibaldi, Assistance Clinical Professor, Director, Prosthetics & Orthotics at University of California, San Francisco (October 23, 2014)

Comment

1. It's increasingly important to this highly vulnerable patient population that we are able to establish higher Medi-Cal rates. We calculated that if we are functioning at 80 percent of Medicare allowable with regard to Medi-Cal reimbursement, we can break even.

Response

Provisions related to reimbursement have remained unchanged and are outside the scope of this regulatory action.

Commenter Name, Title, Organization and Date of Comment(s)

6. Robert Jensen, Laurence Orthopedic (October 23, 2014)

Comment

1. The first thing is that you really would not want a dentist to prescribe your daughter a scoliosis brace and have a pharmacist - - that wouldn't be very effective, and it would be a waste of money for the State to pay for such a device.

Response

Section 51315(a)(1) specifies qualifications related to prescribing and furnishing O&P appliances and services. Subsection (a)(1) specifically notes that a TAR will only be approved if the appliance or service is prescribed or furnished by a provider "…within the scope of their license…" Therefore, the scenario noted by the commenter would not be approved for reimbursement since prescribing a scoliosis brace is not within the scope of a dentist's license as established by the Business and Professions Code.

Comment

2. An example of a definition being too broad would be the dynamic flexor hinge wrist brace, which is made for a very specific brace made for quadriplegics that don't have the ability to grasp. What it does is it harnesses the wrist extensors to enable that hand to close and enable that quadriplegic to eat and write and function. The way that definition is written today leaves it open to definite abuse, maybe fraud. I have a manufacturer that has asked me to bill for that device that they make for post-surgical that doesn't have anything to do with that kind of function and asked me to use that code because that code reimburses high enough to cover the cost of that brace. I have refused to do that. So that would be a situation where those definitions are too broad.

Response

The assumption is that this comment is in reference to Section 51161(gg). This subsection was not amended based on comment.

The Department does not concur that the definition in this subsection is overly broad. Authorization of this appliance requires the documentation of medical necessity for the specific patient and specific appliance as set forth in Section 51315.1(l)(5).

Comment

3. A place where the definition is too narrow would be in the policy for therapeutic shoes in terms of custom insoles. The new regulation calls for either plaster slipper casts or digital rendering of the foot and prohibits the use of a form impression box to get the insole for a diabetic's shoes. To take a slipper cast doubles the amount of time that it takes to make that insole. The insole reimburses at $26.20 minus the ten percent that we're stuck with at this point. By the time you actually dip the plaster in the water you burn through your money already. To put that kind of burden on us is not very feasible. The only resource I would have - - when I read that, the resource I came up with is I cannot do therapeutic shoes for Medi-Cal.

Response

The assumption is that this comment is in reference to Section 51315.1(j)(10)(C) related to custom foot orthoses.

The Department does not concur that the definition for "custom fabricated appliance," Section 51161(z), or the proposed provisions relating to "custom foot orthosis" are too narrow.

Section 51315.1(j)(10)(C) establishes requirements for the fabrication of a custom foot orthosis; specifically that the patient's individual measurements or pattern shall be used to create the custom fabrication. Section 51161(z) defines "custom fabricated appliance" or "custom fabrication" as "an appliance constructed for a specific patient by obtaining individual measurements, fashioning a pattern or creating a mold, using either a plaster cast, or with a positive or negative impression or using a scanning device." This definition applies to all custom fabricated orthoses, not just shoes. As noted in Section 51315.1(j)(10)(C), the use of foam boxes is not an acceptable fabrication method. This method does not produce individual measurements as well as fashioning a pattern, creating a mold, using a plaster cast, a positive or negative impression, or using a scanning device.