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October 29, 2015

Fred Bruyns, policy analyst/rules coordinator
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Via email: fred.h.bruyns@oregon.gov

Re: Helios Recommendations for Advisory Committee Agenda for OAR 436-009, Oregon Medical Fee and Payment Rules

Helios appreciates the opportunity to participate in the rulemaking advisory committee meeting on OAR 436-009 (Oregon Medical Fee and Payment Rules) and OAR 436-010 (Medical Services). As part of this, we would like to recommend an addition to 436-009 regarding the billing and payment for compounded medications. We believe addition of this language will add needed clarity for stakeholders on how to bill and subsequently reimburse for these unique medications. In addition, we also recommend the Division consider establishing a total dollar reimbursement cap on compounds as a means to control costs without hindering access to care for injured workers.

Background

Compounding is an age old process used by pharmacists to create personalized medications to address patients with unique medical needs. It is defined as a combined, mixed, or altered drug prepared for the specific care of one patient. Manufacturers will never be able to produce every medication, in every strength, and every dosage that a patient may require, and this is where pharmaceutical compounding plays a necessary role. For example, if a patient has allergies or other health problems that prevent use of a commercially prepared medication, a compounded medication might be a viable alternative or situation where a compounded medication **may** offer benefits.

In recent years, certain entities – including providers – have realized that compounding in workers' compensation can be a potentially lucrative source of revenue. Research from the California Workers' Compensation Institute (CWCI) showed a quadruple increase in usage of compounded medications from 2006 to 2009, while the average amount paid per compounded medication prescription increased 68.2% from \$460.42 to \$774.21 (2011 to 2012).

As a way of increasing this "lucrative" source of revenue, many compounded medications contain multiple ingredients, some of which may lack a valid NDC or associated AWP. This enables the provider or billing entity to not only circumvent the fee schedule, in many cases, but also inflate the overall cost of a compound by adding ingredients which have little to no therapeutic effectiveness. Helios has seen this lack of ingredient transparency render it difficult if not impossible for the payer to determine what product is being billed for and used by the injured worker. This impacts not only cost, but clinical efficacy and patient safety.



Baseline Standard

As an interesting increase in compound medication utilization has emerged, numerous workers’ compensation agencies across the country have taken several routes to clarify compound billing and reimbursement. As part of this, a rather consistent baseline standard has emerged requiring ingredient-level billing and subsequent reimbursement for compounds based on **each** individual ingredient NDC and associated AWP, and disallowing reimbursement for ingredients lacking an NDC. While the compounded formulation, itself, may not have an assigned NDC, each ingredient within the compound typically does, and each valid NDC will have a valid AWP which can be used for pricing and reimbursement purposes.

This ingredient-level breakdown aligns with the national pharmacy billing standards (paper and electronic) maintained by the National Council for Prescription Drug Programs (NCPDP) which have also been adopted by Oregon for billing of pharmacy transactions. In addition, the standard paper billing form (CMS-1500) and electronic billing format (X12 837 professional) for physicians and other professional providers (both also adopted under the Division’s rules) also enable ingredient-level breakdown of compound medications.

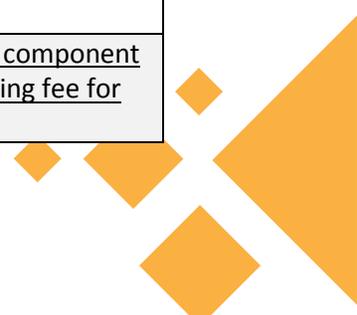
Given this, Helios recommends the Division add language into the Pharmaceutical section of these rules establishing ingredient-level billing and reimbursement as **the** baseline standard for compounds. We specifically recommend the following addition (indicated with underlined text) to 436-009-0090(2)(a):

(2) Pharmaceutical Billing and Payment.

(a) Pharmaceutical billings must contain the National Drug Code (NDC) to identify the drug or biological billed. This includes compounded drugs, which must be billed at the component ingredient level, listing each ingredient NDC. Ingredients without an NDC may not be reimbursed.

To complement this, for subsequent reimbursement we recommend the following addition (indicated with underlined text in a newly inserted row of the table) to the maximum allowable fee table under 436-009-0090(2)(d) accounting for how to reimburse if the drug dispensed is a compound, based on the same pricing benchmark:

If the drug dispensed is:	Then the maximum allowable fee is:
A generic drug	83.5 % of the dispensed drug’s AWP plus a \$2.00 dispensing fee
A brand name drug without a generic equivalent or the prescribing provider has specified that the drug may not be substituted with a generic equivalent	83.5 % of the dispensed drug’s AWP plus a \$2.00 dispensing fee
A brand name drug with a generic equivalent and the prescribing provider has not prohibited substitution	83.5 % of the average AWP for the class of generic drugs plus a \$2.00 dispensing fee
<u>A compounded drug</u>	<u>83.5% of the AWP for each individual component ingredient plus a single \$2.00 dispensing fee for the entire compound</u>



Additional Recommendation

While many jurisdictions have established this ingredient-level billing and reimbursement methodology as a minimum baseline, others have gone further to control an unintended consequence of reimbursing each ingredient, no matter the quantity. Because there can be (and has been in other jurisdictions) an incentive to add more and more ingredients (often inactive ingredients) to a compound to inflate reimbursement, a few jurisdictions have limited reimbursement to compounds containing only a few active ingredients and/or have placed a total dollar cap on reimbursement for **any** compound in addition to the ingredient-level baseline pricing.

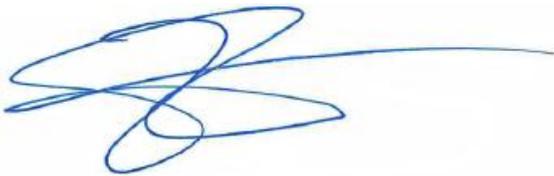
Drawing from this, Helios recommends the Division consider placing an extra total dollar cap on reimbursement in addition to the recommended ingredient-level baseline pricing. We will defer to the Division and stakeholders as to what that specific dollar amount will be – but examples from other jurisdictions have ranged from a total amount of \$300 - \$600 per compound.

Conclusion

To provide additional context, we have attached separately from this letter several examples of states which, for workers' compensation purposes, have adopted regulatory or statutory provisions specific to compound billing and reimbursement. This is by no means a complete list, only a sampling of some of the more recent or more pertinent reforms that could work well in Oregon. We think this abbreviated list sufficiently demonstrates the common themes and variation of approaches taken by these other states' agencies.

Thank you for taking time to consider our comments. We, again, look forward to participating in the upcoming advisory committee meeting. Please let me know if you have any questions or require any additional information related to our recommendations.

Sincerely,



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**Oregon Administrative Rule Revision
Chapter 436, Division 009 and 010**

Issue # ?

Rules: OAR 436-009-0090(2)

Issue: Should WCD add clarifying language stating that billing and reimbursement for compounds should be at the ingredient NDC level and adopt a total dollar reimbursement cap for compounds?

Background:

- Compounds, as a whole, are not assigned NDCs or associated AWP
- WCD rules require that pharmaceutical billings must contain the NDC to identify the drug or biological billed but do not specifically address compounds
- WCD's adopted maximum allowable fees for pharmaceuticals are based on the AWP for the drug
- Individual ingredients within a compound should have assigned NDCs
- National billing standards also adopted by WCD enable billing for compounds at the ingredient level
- There is a concern over billing transparency and costs of compounds in workers' compensation, which several other states have addressed through adopting ingredient-level billing/pricing and/or a total dollar reimbursement cap for compounds

Options:

- Amend OAR 436-009-0090(2) to both clarify billing and reimbursement for compounds should be at the ingredient NDC level and adopt a total dollar reimbursement cap for compounds
- Only amend OAR 436-009-0090(2) to clarify billing and reimbursement for compounds should be at the ingredient NDC level
- No change.
- Other?

Fiscal Impacts, including cost of compliance for small business:

Recommendations:

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In anticipation of the upcoming rulemaking advisory committee on OAR 436-009 (Oregon Medical Fee and Payment Rules) and OAR 436-010 (Medical Services), Helios welcomes the opportunity to provide several pertinent examples of states which, for workers' compensation purposes, have adopted regulatory or statutory provisions specific to compound billing and reimbursement. This is by no means a complete list of state activity on this issue in recent years. The list contains each listed jurisdiction's most relevant regulatory or statutory verbiage along with citations. We hope these examples will provide some context to our recommendations.

- **Arizona**

- Arizona Physicians' And Pharmaceutical Fee Schedule 2015/2016, Pharmaceutical Fee Schedule: "Reimbursement for prescription medicines shall be based on a discount from 'average wholesale price' (AWP). ... For a repackaged or compounded drug, this would be the AWP of the underlying drug product used in the repackaging or compounding. If information pertaining to the original labeler of the underlying drug product is not provided or unknown, then discretion is vested in the payer to select the AWP to use (as published in the nationally recognized pharmaceutical publication designated by the Commission) when making payment for the repackaged or compounded drug. ... A billing for a compound drug shall include the NDC for each underlying ingredient used in the compound."

- **California**

- California Labor Code 5307.1.(e)(2): "Any compounded drug product shall be billed by the compounding pharmacy or dispensing physician at the ingredient level, with each ingredient identified using the applicable National Drug Code (NDC) of the ingredient and the corresponding quantity, and in accordance with regulations adopted by the California State Board of Pharmacy. Ingredients with no NDC shall not be separately reimbursable. The ingredient-level reimbursement shall be equal to 100 percent of the reimbursement allowed by the Medi-Cal payment system and payment shall be based on the sum of the allowable fee for each ingredient plus a dispensing fee equal to the dispensing fee allowed by the Medi-Cal payment systems. If the compounded drug product is dispensed by a physician, the maximum reimbursement shall not exceed 300 percent of documented paid costs, but in no case more than twenty dollars (\$20) above documented paid costs."

- **Georgia**

- The Georgia Workers' Compensation Medical Fee Schedule, Section IV: "Compound medications shall be billed by listing each ingredient, the corresponding NDC, and the quantity. An ingredient for which there is no NDC shall not be reimbursed. For compound medications, reimbursement shall only be considered for preparations that contain not less than one (1), nor more than three (3) active ingredient(s), and the active ingredient(s) must be Food and Drug Administration (FDA) approved. (FDA approved means the New

Drug Application for the active ingredient used has been approved by the FDA and is legal for general use.) ... The maximum allowable reimbursement for the compound shall be the sum of the AWP for each active ingredient minus 50 percent, plus a single compounding fee of \$20.00.”

- **Michigan**

- Michigan Administrative Code R 418.101009: “Topical compound drugs or medications shall be billed using the specific amount of each component drug and its original manufacturers’ NDC number included in the compound. Reimbursement shall be based on a maximum reimbursement of the AWP minus 10% based upon the original manufacturer’s NDC number, as published by Red Book or Medi-Span, and pro-rated for each component amount used. Components without NDC numbers shall not be reimbursed. A single dispensing fee for a compound prescription shall be \$12.50 for a non-sterile compound. The dispensing fee for a compound prescription shall be billed with code WC 700-C. The provider shall dispense a 30-day supply per prescription. Reimbursement for a custom compounded drug is limited to a maximum of \$600.00. Any charges exceeding this amount must be accompanied by the original component manufacturers’ invoice pro-rated for each component amount used, for review by the carrier.”

- **Mississippi**

- Mississippi Administrative Code Title 20, Part 2: “Compound drugs or medications shall be billed by listing each drug and its NDC number included in the compound and calculating the charge for each drug separately. Payment shall be based on the sum of the fee for each ingredient, plus a single dispensing fee of five dollars (\$5.00). ... Reimbursement for a compound cream medication is limited to a maximum total reimbursement of three hundred dollars (\$300.00) for one hundred twenty (120) grams per month. Any additional quantity over and above this one hundred twenty (120) gram limit requires further documentation and prior authorization (pre-certification).”

- **Ohio**

- Ohio Administrative Code 4123-6-21.1: “For non-sterile compounded prescriptions, the product cost component shall be limited to the lesser of the usual and customary price or the AWP of the commonly stocked package size minus nine per cent for each ingredient. The maximum product cost component reimbursement for any one compounded prescription will be six hundred dollars. ... The dispensing fee component for non-sterile compounded prescriptions shall be twelve dollars and fifty cents.”

