Hearing Summary Report

Hearing Date: 06/03/2021 Today's Date: 06/07/2021

Agency: Ohio Bureau of Workers' Compensation

Rule Number(s): 4123-6-21 and 4123-6-21.3

If no comments at the hearing, please check the box:

List organizations or individuals giving or submitting testimony before, during or after the public hearing and indicate the rule number(s) in question:

4123-6-21 of the Administrative Code:

Comment by Kelly Shank of the OAAPN:

Ms. Shank requested changing references in paragraphs (F) and (J) of the rule from "physician" to "provider" to clarify prescription of medication to injured workers.

BWC's response to Ms. Shank:

BWC provides reimbursement for prescriptions written by BWC certified providers including APRNs, and our proposed rule changes will have no impact on reimbursement based upon provider type. During our next review of this rule we will examine references to "physician" in this rule and update to provider neutral language where it is necessary.

Language addressing "physician of record" in section (F) of this rule will not be modified. The physician of record is responsible for creating a comprehensive treatment plan for the injured worker, and the expectation is that it must be a physician. This does not prohibit an APRN who is BWC certified from treating and prescribing medication to the injured worker in accordance with the treatment plan. We are happy to discuss this comment in more detail.

Paragraph (J) of the rule which addresses "dispense as written" will be updated from "physician" to "provider" during our next review of this rule. We currently apply this rule to any BWC certified provider who writes "dispense as written" on an injured worker's prescription, including APRNs. The language will be updated to reflect all prescribing provider types.

Comment by Ernie Boyd of the OAP:

Mr. Boyd strongly objects to the changes in this rule, regarding compounded medications, noting "*[w]e are still in the middle of an opioid epidemic in Ohio, and we feel confident that these products have kept some patients from moving to narcotics*," and indicating they "*would like to see the changes in this rule rescinded until we have a chance to speak directly with the department about the issues raised by this rule change.*"

BWC's response to Mr. Boyd:

BWC is not aware of any evidence that establishes topical compounds as an effective means to prevent or reduce opioid prescribing and opioid use. If you have any evidence that supports that statement, please share it with me. BWC will maintain formulary coverage for numerous non-

opioid pharmacologic products that may be used for treatment of pain including; oral and topical non-steroidal anti-inflammatory drugs, topical anesthetics, corticosteroids, non-opioid analgesics, tricyclics, duloxetine, anticonvulsants, muscle relaxants, and a number of over the counter topical pain remedies.

The decision to remove coverage of non-sterile compounds resulted from a recommendation from our Pharmacy & Therapeutics (P&T) Committee in January 2021. All committee members present voted in favor of removing coverage, with the exception of one member who recused himself from voting due to conflict of interest. Whenever our P&T Committee examines a medication or class of drugs we first consider safety and efficacy, and our evaluation of non-sterile compounds followed the same structure. To provide you more context I would like to highlight two recent studies that were considered by our P&T committee when forming the recommendation. Here is a quick summary of both studies:

- The first study is a randomized controlled trial funded by the US Department of Defense published in 2019 which examined effectiveness of topical compounded preparations to placebo for treatment of neuropathic, nociceptive, or mixed pain and 399 patients participated. Compound ingredients studied included ketamine, gabapentin, clonidine, lidocaine, ketoprofen, baclofen, cyclobenzaprine, and diclofenac. The study found that the compounded pain creams were not better than placebo creams. (Brutcher RE, Kurihara C, Bicket MC, et al. Compounded Topical Pain Creams to Treat Localized Chronic Pain: A Randomized Controlled Trial. Ann Intern Med. 2019 Mar 5;170(5):309-318.)
- The second study (attached) was published in 2018. The FDA requested The National Academies of Sciences, Engineering, Medicine (NASEM) perform an analysis relating to ingredients used in topical compounded pain creams. NASEM provided the FDA with its analysis of compounded topical pain creams on May 13, 2020. The report concludes that there is limited evidence to support their use in the general adult population, and inadequate data to support conclusions regarding safety.

The FDA has not evaluated and approved non-sterile compounds, there is an absence of data to establish efficacy, and there is an absence of data to support safety. For these reasons the recommendation was made to remove coverage.

Another concern brought up by Mr. Boyd was not receiving notification of the proposed changes. Mr. Boyd is included on BWC's stakeholder email list, and was sent a copy of the proposed changes in a February 5, 2021 email.

Comment by Matthew J. Buderer of Buderer Drug Co.,:

Mr. Buderer indicates he is "*concerned that BWC is eliminating a therapy modality when there are few options available for the treatment of pain*," and suggests BWC conduct a satisfaction survey of BWC IWs receiving "*compounded pain management therapies*" to evaluate their value.

BWC's response to Mr. Buderer:

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The decision to remove coverage of non-sterile compounds resulted from a recommendation from our Pharmacy & Therapeutics (P&T) Committee in January 2021. All committee members present voted in favor of removing coverage, with the exception of one member who recused himself from voting due to conflict of interest. When our P&T Committee examines a medication or class of drugs we first consider safety and efficacy, and our evaluation of non-sterile compounds followed the same structure. To provide you more context I would like to highlight two recent studies that were considered by our P&T committee when forming the recommendation. Here is a quick summary of both studies:

- The first study is a randomized controlled trial funded by the US Department of Defense published in 2019 which examined effectiveness of topical compounded preparations to placebo for treatment of neuropathic, nociceptive, or mixed pain and 399 patients participated. Compound ingredients studied included ketamine, gabapentin, clonidine, lidocaine, ketoprofen, baclofen, cyclobenzaprine, and diclofenac. The study found that the compounded pain creams were not better than placebo creams. (Brutcher RE, Kurihara C, Bicket MC, et al. Compounded Topical Pain Creams to Treat Localized Chronic Pain: A Randomized Controlled Trial. Ann Intern Med. 2019 Mar 5;170(5):309-318.)
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Further, your concerns regarding the availability of pain treatment options. BWC will maintain formulary coverage for numerous non-opioid drugs that may be used for treatment of pain including; oral and topical non-steroidal anti-inflammatory drugs, topical anesthetics, corticosteroids, non-opioid analgesics, tricyclics, duloxetine, anticonvulsants, muscle relaxants, and a number of over the counter topical pain remedies. I am not aware of any evidence that establishes topical compounds as an effective means to prevent or reduce opioid prescribing and opioid use. If you are aware of evidence that does establish topical compounds as an effective treatment that prevent opioid use, please share it with me and I will review.

The FDA has not evaluated and approved non-sterile compounds, there is an absence of data to establish efficacy, and there is an absence of data to support safety. For these reasons the recommendation was made to remove coverage. In the future, if quality evidence for these products becomes available our P&T Committee may revisit this topic.