2021 House Bill No. 1139
Testimony before the Senate Industry, Business and Labor Committee
Presented by Tim Wahlin
Workforce Safety and Insurance
March 8, 2021

Mr. Chairman and Members of the Committee:

My name is Tim Wahlin, Chief of Injury Services at WSI. I am here today to provide testimony regarding House Bill No. 1139. The WSI Board supports this bill.

House Bill 1139 creates controls over two types of medications commonly prescribed to injured employees following a work-related injury. Each of these medications, given long-term, present significant problems including dependency, an increasing likelihood of addiction, increased sedation and respiratory depression, especially when used concurrently.

This bill was developed and heard in the 2019 Legislative Assembly. It was amended in Committee and then failed in the House by a narrow margin. The bill before you is the amended bill from the 2019 Legislative Assembly.

The 2019 bill was developed after numerous consultations with North Dakota physicians.

A 2016 New England Journal of Medicine article summarizes the risks and scope of impacts opioid medications carry. The article concludes the risk of dependence may be as high as twenty-six percent of patients receiving opioids for non-cancer related pain. N Engl J Med. 2016 Apr 21:374(16):1501-1504. Overall, one of every 550 patients who start an opioid therapy die of opioid related causes. Id. This increased to one in thirty-two patient deaths for those receiving doses of 200 MME or higher. Id. The authors conclude they "know of no other medication routinely used for a nonfatal condition that kills patients so frequently." Id. WSI currently has thirty-one injured employees receiving opioid doses of 300 MME or higher and thirteen of those are at or above 500 MME. (See appendix 1).

Currently the United States is in the midst of an opioid epidemic. Deaths from overdose have exceeded deaths related to traffic accidents. Opioids are not the only medications that are plagued with misuse and abuse and this legislation addresses others as well. Collectively, we are discovering in order to meaningfully address this issue, there needs to be changes.

WSI has taken steps to control and limit the widespread, long-term use of opioids in particular, but this legislation will continue to advance that mission and hopefully limit the devastating consequences dependency brings to our injured employees.

The basis of this legislation was a recommendation from the 2018 Performance Evaluation of North Dakota Workforce Safety & Insurance, performed by Sedgwick. The report recommended opioid caps, not only on the initial fill during the acute phase of treatment, but also on the continued use of opioid medications into the chronic phase of treatment. The Interim Workers' Compensation Review Committee received Sedgwick's report in 2018, and directed legislation be drafted.

The first medication the bill addresses is opioid and opioid-like medications. The legislation follows medical evidence that challenges the efficacy of long-term opioid use for the treatment of chronic pain and recognizes the increasing likelihood of dependency and the devastating consequences that can entail as well as the alarming rise in opioid-related deaths. The bill will limit the maximum day supply which can be obtained in the first thirty days of therapy to seven days of medication at a time. This limit will minimize opioid medications in circulation and keep unnecessary prescriptions from being distributed. The seven day fill is also consistent with the fill programs for Medicaid administered by the N.D. Department of Human Services.

In addition, the bill establishes a cap on the strength of the opioids prescribed. Because opioid medications vary widely in potency, in order to accurately compare medications, each has to be compared to an existing drug, in this case morphine. The industry has created measures of "morphine milligram equivalents (MME)." Each medication has a conversion factor. As an example, 1mg of oxycodone is equivalent to 1.5mg of morphine. This bill sets a cap for an amount not to exceed 90 MME. This level was chosen based upon the Sedgwick evaluation. After reviewing the literature, Sedgwick determined that dosing above 90 MME equivalents constitutes high dosages and significantly increases the risk or likelihood of potentially fatal adverse effects. This practice matches similar dosing limits throughout the healthcare industry. In fact our state employee health coverage has similar provisions and in fact more stringent limitations on short term dosing.

The proposed legislation specifically exempts certain applications where the risk of overdose or dependency is muted. For example, applications when there is direct supervision of the administration or the likelihood dependency is not an issue, such as end of life care.

The second medication the bill addresses is benzodiazepine therapy extending beyond a cumulative duration of four weeks. Like opioid therapies, benzodiazepine therapies cause mood alteration and can lead to habituation and dependence, and in most circumstances lose effectiveness in a relatively short period of time. Studies have shown that in the United States there is a high likelihood of abuse and misuse potential for these medications. Medical science likewise recognizes the very challenging, and often long-term process of recovery to reverse this course. In rare circumstances, long-term therapies of benzodiazepine for treating certain types of anxiety disorders may be appropriate and this is recognized in the legislation.

The final proposed regulation addresses when the two substances are used in combination. When used in combination the chance for a fatal overdose increases dramatically. In combination they will not only sedate but will also depress respiration, an obviously dangerous combination.

Finally, the bill allows for the organization to depart from these limits "upon a showing of medical necessity." This review system is described at NDCC 65-02-20, WSI's managed care statute. This will create flexibility to accommodate cases that present special medical circumstances where the statute would otherwise deny the therapy drug.

Section 2 is the application portion of the bill. The application is different for injured employees receiving any therapy exceeding the therapy limits. The application directs all injured employees to be in compliance by July 1, 2022. This will give both providers and injured employees notice and over a year to reach compliance.

We know that the deaths are directly correlated with dosage levels. In a recent data snapshot, WSI has 153 injured employees receiving more than 90 MME. Of those ninety, thirty-one are at

or above 300 MME, and thirteen are at or above 500 MME. It is unlikely this legislation will reach many of these injured employees because they may well qualify for departure due to a medical necessity. However, it is anticipated it will reach some injured employees. More importantly, it is anticipated it will prevent these trends from repeating.

This concludes my testimony and I will be happy to answer any questions you may have.

Appendix 1.

Daily Morphine Equivalent	Total
91 – 150	65
151 – 300	57
301 – 500	18
> 500	13
	153
ND Residents	124
Other States	29
	153

OPTUMRx®

Quantity Limit Changes on Short-Acting Opioids

Applies to select OptumRx Commercial clients

Effective July 1, 2017

As part of the standard OptumRx formulary update process, select commercial clients with members utilizing brand or generic short-acting opioid medications are subject to the following quantity limit changes. These updates align with the new Centers for Disease Control and Prevention (CDC) guidelines released in 2016, as well as clinical-based prescribing recommendations for Morphine Milligram Equivalent (MME) dosing.

As outlined below, there will be separate limits for members new to therapy and those who are existing opioid utilizers:

New to therapy member limits on short-acting opioids
Members naïve to opioid therapy (no opioid in their most recent 120-day claims history) are limited to a maximum of 49 MME per day; up to two 7-day supplies within a 60-day timeframe.

Treatment experienced member limits on short-acting opioids
Members NOT new to therapy (have filled opioids in their most recent 120-day claims history) are limited to a maximum of 90 MME per day and subject to two fills within a 60-day timeframe.

Edits will first screen the past 360 days of a member's profile for oncology drugs and will not initiate a quantity limit if one is found.

Effective 7/1/18: 4 products added to short-acting opioid (SAO) quantity limit program

- Ultram (tramadol) tablets, Ultracet (tramadol-acetaminophen) tablets, Butorphanol nasal spray, Levorphanol tablets

Effective 10/1/2018: Short-acting opioid (SAO) utilization management edit to restrict treatment naïve (new to therapy) members age 19 and younger to no more than a 3-day supply.

"Adolescents who misuse opioid pain medication often misuse medications from their own previous prescriptions, with an estimated 20% of adolescents with currently prescribed opioid medications reporting using them intentionally to get high or increase the effects of alcohol or other drugs."[1]

PRESCRIBE SHORT DURATIONS FOR ACUTE PAIN[1]
"Clinicians should prescribe opioids at the lowest effective dose and for no longer than the expected duration of pain severe enough to require opioids to minimize unintentional initiation of long-term opioid use. **Three days or less will often be sufficient;** more than seven days will rarely be needed."[1]

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Quantity Limit Changes on Short-Acting Opioids

We encourage prescribers to practice safe prescribing through the recommendations of the CDC without fully restricting their practice, and allowing appropriate prescribing on a case by case basis.

As always, prescribers are able to utilize the prior authorization process for those patients whose clinical diagnosis may require high quantities or ongoing therapy.

Commonly prescribed short-acting opioids and maximum fill limits

Brand Name	Drug Label Name	Morphine Equivalent Dose of 49 mg Units/Day	Morphine Equivalent Dose of 90 mg Units/Day
ROXICODONE	OXYCODONE TAB 30MG	1	2
PERCOCET, ENDOCET	OXYCOD/APAP TAB 10-325MG	3	6
LORTAB, LORCET, NORCO	HYDROCO/APAP TAB 10-325MG	4	9
LORTAB, LORCET, NORCO	HYDROCO/APAP TAB 5-325MG	9	12
PERCOCET, ENDOCET	OXYCOD/APAP TAB 5-325MG	6	12

When these edits are encountered
Pharmacies and prescribers should follow applicable federal or state dispensing guidelines for dispensing controlled substances.
Specific to CII dispensing, either:

- Cut back the quantity to the limit permitted, cancelling the remainder of the units on the script OR
- Dispense an emergency 1-2 day supply, while PA is sought for the higher volume if justified

References:
Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. [illegible]

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Quantity Limit Changes on Short-Acting Opioids

Prior Authorization may be pursued if clinically necessary
Additional treatment/increased quantities will be approved when the following criteria are met:

1. One of the following:
    - 1.1. Diagnosis of Cancer OR
    - 1.2. Patient is receiving opioids as part of end of life care OR
    - 1.3. All of the following:
        - 1.3.1. The prescriber certifies that there is an active treatment plan that includes but is not limited to a specific treatment objective and use of other pharmacological and non-pharmacological agents for pain relief as appropriate AND
        - 1.3.2. The prescriber certifies that there has been an informed consent document signed and an addiction risk assessment has been performed AND
        - 1.3.3. The prescriber certifies that a written/signed agreement between prescriber and patient addressing issues of prescription management, diversion, and the use of other substances exists, OR
    - 1.4. Post-Operative Pain Management (all of the following):
        - 1.4.1. Medication is being used to treat postoperative pain, AND
        - 1.4.2. Medication is not being prescribed for pain related to a dental procedure, AND
        - 1.4.3. The dose being prescribed is the dose that the patient was stable on prior to discharge