House Industry Business and Labor Committee

House Bill 1139

67th Legislative Assembly of North Dakota

A Michael Booth MD PhD FACS

On behalf of the North Dakota Medical Association

Chairman Lefor and Members of the Committee:

My name is Mike Booth. I am a practicing, board certified cardiovascular and thoracic surgeon in Bismarck. My practice includes the evaluation and management of many patients with chronic pain, particularly back pain, who have been referred for evaluation of possible associated cardiovascular disorders. This experience and training has given me extensive exposure to the clinical problems addressed in this legislation. Additionally, I have personally experienced problems with chronic back pain and have in fact undergone surgery for a herniated disc.

North Dakota Workforce Safety and Insurance (WSI) dates to 1916. Its purpose is to care for injured workers.[1] It serves as the "exclusive, employer financed, no fault insurance state fund covering workplace injuries, illnesses, and death in North Dakota. As such, WSI assumes liability for the treatment, rehabilitation and support of workers injured on the job. In many instances, this may be for the remainder of the worker's life. WSI is the sole provider and administrator of the workers compensation system[2]." As such, it is a state operated monopoly whose administrators are appointed by the Governor. Its actions are governed by this Legislature, which has the power to enact laws to enforce this monopoly. As such this body needs to exercise great care and judgement in how it chooses to exercise its power to influence the day-to day operation of WSI. Authoring a law to achieve an otherwise well-intentioned goal is not always the best solution.

This bill seeks to place a flat limit of 90 morphine mg equivalents limits daily for no more than seven days of opioid therapy during the first 30 days of outpatient treatment for an

[1] North Dakota WSI website 1/17/21

[2] North Dakota WSI website 1/17/21

injury with some exceptions that are low probability. This duration of treatment would likely be inadequate for recovery from many surgical procedures. It also flatly prohibits authorization for payments for benzodiazepine therapy beyond 4 weeks except for WSI approved therapy for anxiety disorders. Combination therapies are similarly restricted. The bill provides only limited exceptions to this which must be resolved through the dispute resolution process.

The opioid restrictions are in addition to previous legislation implemented in 2015 governing the ongoing administration of chronic opioid therapy. That action arose out of concerns about the overuse of opiates for the treatment of chronic pain, opiate addiction related to this treatment and outright abuse and diversion of these medicines for illegal consumption. These were all in response to what has become labeled the "opioid crisis" confronting our state and nation. Your NDMA has been very actively involved in its efforts to mitigate this crisis, particularly in the area of prescription drug abuse and the emergency management of opiate overdoses and has been very supportive of these efforts.

A bill very similar to this was introduced 2 years ago and defeated.

Some background:

Morphine milligram equivalents: There are many prescription opioids that are used to treat pain. Morphine milligram equivalents are used to compare a given narcotic's potency relative to morphine. For instance, it takes 6.67 mg of codeine to equal the effect of 1 mg of morphine. A standard dose of 30 mg codeine would equal 4.5 mg of morphine. For hydromorphone (Dilaudid), a standard dose of 1 mg of Dilaudid is equivalent to 4 mg of morphine. As a practical matter, if you are sent home from surgery with a prescription for 4 Tylenol # 3 per day, you would be taking 18 MME's per day. A prescription of 2 mg of Dilaudid 6 time a day would be 48 MME's. These potencies refer to peak effectiveness. The duration of effectiveness varies considerably with different narcotics.

The number 90 MME's was set by the CDC as a suggested upper limit for most pain prescriptions. Above that, the CDC recommends that the dosage should be justified with appropriate documentation. In clinical practice, there are times when more MMEs are very appropriate. Conversely, there are times when it is too much. Indeed, newer data suggests that 50 MME's might be more appropriate for longer term use of narcotics. Cost of these medications does not seem to be a significant impetus

for this bill (HB1139). In any event, there is already a formulary mechanism in place to keeps costs down. Our concern with this bill is that it flatly denies payment for higher doses, whether or not the prescriber is able to justify the dosage and arbitrarily limits the duration of treatment. We believe this limit is more properly a case management responsibility for WSI, rather than a matter of law imposed by the Legislature.

Benzodiazpines:

These drugs are interrelated in their chemistry and pharmacology. Their primary use is for short-acting sedation. Most benzodiazepines are effective as muscle relaxers and may in fact be indicated for either sedation or as a muscle relaxant for an injured worker. As a class, benzodiazepines do have potential for abuse. There are also drugs classed as muscle relaxers that are not benzodiazepines. While all of the muscle relaxers are prescription drugs, not all are scheduled drugs and their effects are more variable. I would personally try to use one of the relaxers as a first choice, but it may not be appropriate in every situation. Setting a flat 4-week limit for the use of benzodiazepines is medically improper. Three months is probably a better time frame to allow recovery from non-surgical back pain. As one who suffers from back spasms, particularly after a long day in the operating room or just working around the house, I can tell you that symptoms can linger on for months following an injury, but they fortunately are not normally constant. Again, our position is that their coverage by WSI should be a matter for proper case management rather that legislative prohibition. Until the symptoms produced by the injury are resolved, it is only fair that coverage be continued. Remember that WSI is responsible for the treatment of that injury. A thirty-day statutory cutoff is arbitrary and violates the organization's covenant with our state's workers

What has changed in the last two years?

North Dakota has made considerable progress in the past decade in our understanding of the use of drugs that have potential for abuse. Our state does have ready access to data on the use of prescription drugs through improved formulary management and systems such as the Prescription Drug Management Program (PDMP). All physicians, physician extenders and pharmacists are required to be registered for the PDMP. During the past 2 years, the reliability of the program in identifying prescription drug abusers has greatly improved. Access to the PDMP has also now been incorporated into the electronic health records systems for most of our health care providers. Gabapentin and Pregabalin (Lyrica), two other drugs with some abuse potential, have also now been included in the state's PDMP reporting system.

Guidelines clarifying the use of the PDMP have also been put in place. Interestingly, the recommendation for investigating outpatient opioid use does not begin until 12 weeks after the first prescription, which is considerably more generous than the time allotment in this bill.

Formulary management programs have also become increasingly sophisticated. WSI already has in place such a program, with just about every opioid and benzodiazepine I can think of being listed in its pages. The Formulary classifies drugs as covered, non-covered, in some instances limits to maximal daily doses and in other cases, provides for prior authorization for prescription approval. Among my other duties, I serve as a member of this state's Medicaid Drug Utilization Review Program. **The implementation and management of the Formulary program by Medicaid has had a dramatic effect in reducing the use of these medications and it has all occurred without any statutes placing limits on the use of the specific medications or limits on the length of time for which they may be prescribed. Rather the limits have been developed administratively by the Medicaid program with the approval of the Drug Utilization Review committee.**

Our recommendation:

Rather than imposing these rather arbitrary statutory limits on opioid and benzodiazepine prescriptions, WSI be empowered through its existing formulary and case review program develop guidelines for the use and regulation of these medications, with appropriate input from medical professionals. Prior authorization and PDMP reviews can and should be put in place to identify potential situations where diversion of drugs may be happening. These measures may also be used to encourage providers to consider alternate pain management strategies to hopefully steer patients away from courses of treatment that might be more likely to eventuate in addiction or abuse.

On behalf of the NDMA, I urge you to not pass this measure as presently proposed. Our organization would be happy to work with you on amendments this bill to achieve what we believe are our shared goals to control opioid and benzodiazepine abuse and addiction without compromising WSI's commitments to our state's workers.

Appendix:

MME Conversion Factors

CMS.gov

Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors[1,2]

Type of Opioid (strength units)	MME Conversion Factor
Buprenorphine film/tablet[3] (mg)	30
Buprenorphine patch[4] (mcg/hr)	12.6
Buprenorphine film (mcg)	0.03
Butorphanol (mg)	7
Codeine (mg)	0.15
Dihydrocodeine (mg)	0.25
Fentanyl buccal or SL tablets, or lozenge/troche[5] (mcg)	0.13
Fentanyl film or oral spray[6] (mcg)	0.18
Fentanyl nasal spray[7] (mcg)	0.16
Fentanyl patch[8] (mcg)	7.2
Hydrocodone (mg)	1
Hydromorphone (mg)	4
Levorphanol tartrate (mg)	11
Meperidine hydrochloride (mg)	0.1
Methadone[9] (mg)	
>0, <= 20	4
>20, <=40	8
>40, <=60	10
>60	12
Morphine (mg)	1
Opium (mg)	1
Oxycodone (mg)	1.5
Oxymorphone (mg)	3
Pentazocine (mg)	0.37
Tapentadol [10] (mg)	0.4
Tramadol (mg)	0.1

[1] The MME conversion factor is intended only for analytic purposes where prescription data is used to calculate daily MME. It is to be used in the formula: Strength per Unit X (Number of Units/ Days Supply) X MME conversion factor = MME/Day. This value does not constitute clinical guidance or recommendations for converting patients from one form of opioid analgesic to another. Please consult the manufacturer's full prescribing information for such guidance. Use of this file for the purposes of any clinical decision-making warrants caution.

[2] National Center for Injury Prevention and Control. CDC compilation of benzodiazepines, muscle relaxants, stimulants, zolpidem, and opioid analgesics with oral morphine milligram equivalent conversion factors, 2016 version. Atlanta, GA: Centers for Disease Control and Prevention; 2016. Available at https://www.cdc.gov/drugoverdose/media/. For more information, send an email to Mbohm@cdc.gov.

[3] Buprenorphine formulations with a FDA approved indication for Medication Assisted Treatment (MAT) are excluded from Medicare's Overutilization Monitoring System's opioid overutilization reporting.

[4]The MME conversion factor for buprenorphine patches is based on the assumption that one milligram of parenteral buprenorphine is equivalent to 75 milligrams of oral morphine and that one patch delivers the dispensed micrograms per hour over a 24 hour day. Example: 5 ug/hr buprenorphine patch X 24 hrs = 120 ug/day buprenorphine = 0.12 mg/day = 9 mg/day oral MME. In other words, the conversion factor not accounting for days of use would be 9/5 or 1.8.
However, since the buprenorphine patch remains in place for 7 days, we have multiplied the conversion factor by 7 (1.8 X 7 = 12.6). In this example, MME/day for four 5 µg/hr buprenorphine patches dispensed for use over 28 days would work out as follows: Example: 5 ug/hr buprenorphine patch X (4 patches/28 days) X 12.6 = 9 MME/day. Please note that because this allowance has been made based on the typical dosage of one buprenorphine patch per 7 days, you should first change all Days Supply in your prescription data to follow this standard, i.e., Days Supply for buprenorphine patches= # of patches x 7.

[5]The MME conversion factor for fentanyl buccal tablets, sublingual tablets, and lozenges/troche is 0.13. This conversion factor should be multiplied by the number of micrograms in a given tablet or lozenge/troche.

[6]The MME conversion factor for fentanyl film and oral spray is 0.18. This reflects a 40% greater bioavailability for films compared to lozenges/tablets and 38% greater bioavailability for oral sprays compared to lozenges/tablets.

[7]The MME conversion factor for fentanyl nasal spray is 0.16, which reflects a 20% greater bioavailability for sprays compared to lozenges/tablets.

[8] The MME conversion factor for fentanyl patches is based on the assumption that one milligram of parenteral fentanyl is equivalent to 100 milligrams of oral morphine and that one patch delivers the dispensed micrograms per hour over a 24 hour day. Example: 25 ug/hr fentanyl patch X 24 hrs = 600 ug/day fentanyl = 60 mg/day oral morphine milligram equivalent.
In other words, the conversion factor not accounting for days of use would be 60/25 or 2.4.
However, since the fentanyl patch remains in place for 3 days, we have multiplied the conversion factor by 3 (2.4 X 3 = 7.2). In this example, MME/day for ten 25 µg/hr fentanyl patches dispensed for use over 30 days would work out as follows:
Example: 25 ug/hr fentanyl patch X (10 patches/30 days) X 7.2 = 60 MME/day. Please note that because this allowance has been made based on the typical dosage of one fentanyl patch per 3 days, you should first change all Days Supply in your prescription data to follow this standard, i.e., Days Supply for fentanyl patches= # of patches X 3.

[9] https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[10] Tapentadol is a mu receptor agonist and norepinephrine reuptake inhibitor. Oral MMEs are based on degree of mu-receptor agonist activity, but it is unknown if this drug is associated with overdose in the same dose-dependent manner as observed with medications that are solely mu receptor agonists