A Drug Formulary Dialogue Feb 16, 2016

I had the privilege of testifying for the Nebraska Business & Labor Committee last Monday (Feb 8) on LB 1005 that would require the Nebraska Workers' Compensation Court to adopt an evidence-based drug formulary. It was cold in Lincoln that day but rather heated inside the chambers. Sen. Burke Harr is the sponsor of this legislative bill. He is also the chairman of the Committee, so the Vice-Chair of the Committee, Sen. Dave Bloomfield, managed the proceedings.

The bill is directive but not very specific, as a legislative bill should be. Following the good example set forward by other states, the details will be in the associated rules, debated and propagated by the Nebraska Workers' Compensation Court. In case it's not obvious, the reason that's a good idea is to give flexibility to the Court to create and tweak the rules without needing legislative changes each time. Of course, the lack of detail leaves open the possibility of (mis)interpretation and that was on display.

After an introduction of the bill at the hearing by Sen. Harr on the purpose and scope of the bill, three testified as proponents, five testified as opponents, and one testified as neutral. **I spoke as a proponent**. Each speaker was granted five minutes, and every speaker took that entire allotment. Interestingly, after my testimony, there were no follow-up questions from any of the Senators on the Committee. Sen. Bloomfield, said, with a chuckle, "Looks like nobody wants to test you." I was preceded as proponents by the National Federation of Independent Business and Nebraskans' for Workers' Compensation Equity and Fairness. The upside of proponents going first is they can set expectations. The downside is that opponents can provide a rebuttal. So, since I didn't have a chance to offer rebuttal to the opponents, and since their arguments are similar to ones I've heard in other states, I thought it might be useful to provide that rebuttal here.

NOTE: Because it's not just doctors who prescribe drugs but also Nurse Practitioners and Physician Assistants and Dentists and others, I use the broader term "prescriber" below.

Have a seat and get a cup of coffee because this is going to take awhile!

- (NMA) **Schedule II-V drugs is too broad of a list** - This requirement is listed in the bill's language and as it reads would seem to indicate all such drugs are excluded. That would be inaccurate. I'm confident not all Schedule II-V drugs will be either excluded or included, regardless of the evidence-based medicine (EBM) choice (Official Disability Guidelines, Reed Group, or something custom built for Nebraska).
- (NMA) **LB 471, a bill that would enhance the state's PDMP, is a better initial step** - I do not disagree. This bill is sponsored by Sen. Sara Howard, a member of the Committee and present at the hearing. I have been a long-time proponent of PDMP's, and it appears as though Nebraska's PDMP is not robust enough yet. Sen. Howard stated in this article that

"the bill would close loopholes in the existing PDMP without a cost to the state." Sounds like a no-brainer to me and I would be fully supportive of that bill.

- (NMA) **Injured workers can't be cut "cold turkey" from their existing drug regimens** - Exactly. Which is why, in my testimony, I talked about treating new and "legacy" claims differently and that a remediation period is required to help wean those on inappropriate drug regimens. This is a concern raised by all opponents of drug formularies in every state, and a legitimate concern. The bill, as written, does not require that. As in other states, there is an apparent level of distrust that an issue not explicitly covered in the bill's language will properly be addressed during the rule-making process. Adding in that language (Oklahoma unfortunately did notaddress it but Texas and Tennessee did, and California will soon) is a no-brainer.
- (NMA) **Pain contract should be part of the process** - Absolutely. That is a best practice, not mandated but certainly encouraged, around the country. Unfortunately, some times a pain contract (aka opioid treatment agreement) is used with a "zero tolerance policy" as a means to kick a patient out of the practice when non-compliant. The best use of a contract/agreement is for the prescriber to set the expectations for the patient up-front and if non-compliant to counsel them into compliance. In other words, it should always be a source of dialogue. This should definitely be part of the package when managing patients on potentially dangerous drug regimens but is outside the scope of a drug formulary.
- (Injured worker advocate) **It will interfere with doctor-patient relationship** - Absolutely not. Well, kinda. This comment, stated frequently around the country, shows a misunderstanding of EBM and the role of a drug formulary. They are there to help educate the prescriber on all available treatment options and select the one whose objective clinical studies indicate better results with less side-effects. It is not "cookbook medicine" as if often the assertion. Medicine is a very large subject matter that changes often, so having access to a repository of the best evidence allows a prescriber to make the best decision. As an example offered during my testimony, the use of Soma (carisoprodol) declined by over 90% immediately because it was excluded by the Texas drug formulary. *Is that a good thing? Absolutely.* I dare you to read this Fast Facts document from the Department of Justiceabout Soma (carisoprodol) abuse and tell me that it's less dangerous or more clinical appropriate than other muscle relaxants that are typically included in a drug formulary list. Unfortunately, I've seen hundreds of injured workers who have Soma (carisoprodol) included in their drug regimen - very few are highly functioning human beings. *Should someone "interfere" in the doctor -patient relationship when dangerous drugs are prescribed, over and over again, with no improvement in function or quality of life?* **Yes**.
- (Injured worker advocate) **ProPublica articles** - The self-appointed "watchdog" over Work Comp was invoked as a way to discredit the entire industry and bring into doubt the motivation behind a drug formulary. Are there employers or insurance carriers or vendors that some times don't do the right thing, either by mistake or on-purpose? Yes. Are there injured workers that perpetrate Work Comp fraud or aren't really interested in returning to

work? Yes. Are there prescribers who are more concerned about revenue generation (e.g. physician dispensing) in a fee-for-service model than the benefit to the patient? Yes. Are there lawyers who encourage questionable medical care so their contingency-based fees are increased? Yes. Are these "bad actors" a majority in Work Comp? Absolutely not. We don't live in a perfect world, and Work Comp is not a perfect system, but trying to use anecdotal examples (however true they may be) to impugn the motivations of any stakeholder is not constructive.

- (Orthopedic Surgeon) **Doctors have been sued for not properly treating pain** - True. Starting in 1995 when the FDA approved Purdue Pharma's new OxyContin drug, a robust marketing effort was launched and based largely on the "fact" that it had a less than 1% chance of being addictive (read "How the American opiate epidemic was started by one pharmaceutical company" about how prescribers were misled). Also in the mid-1990's, "pain" was added as the "fifth vital sign." Leading up to those seminal moments, prescribers were accused of under-treating pain and having an opioid phobia. Combine all that (including the lawsuits) and we're now paying for it with what the CDC classifies as an "epidemic" of the use/misuse of prescription drugs (especially those for "pain"). I understand how difficult it can be, that fine line of doing the right thing, which might mean the patient doesn't get the treatment they think they need/deserve. But defensive medicine isn't always the answer. I have never envied the job of a doctor. But that's one reason why a drug formulary can help because it enhances the selection of the treatment option with the largest clinical efficacy and the smallest risk.
- (Orthopedic Surgeon) **The Y / N drug list is too binary** - The concept of included ('Y') and excluded ('N') drugs is most important to facilitate the automated inclusion of a drug formulary in Pharmacy Benefit Manager (PBM) adjudication systems. However, as I mentioned in my testimony, a 'Y' classification does not always mean the drug is clinically appropriate. Similarly, a 'N' classification does not always mean the drug is clinicallyinappropriate. A properly constructed drug formulary will grant an opportunity to the prescriber to prove that a 'N' drug is the correct choice for the patient's condition at this time while allowing the payer to question whether the 'Y' drug is the best clinical option. *That means a robust and consistent dispute resolution process is necessary to ensure that both parties have the opportunity to prove their point*. This comment shows a lack of understanding. Resolving this issue can be addressed during the rule-making process.
- (Orthopedic Surgeon) **No doctor input to the drug list** - This appears to be a concern that the Nebraska Medical Association (NMA) and individual doctors were not involved in the development of this bill. I don't know if that's true or not. Inclusion of all stakeholders, especially the medical community, from the beginning was key to adoption (and the ultimate success) in Texas. Not only were the Texas Medical Association and Texas Pain Society part of the design process, but their active feedback was also key to pre- and post-implementation. The same has been true in California and Tennessee. Did that complicate, and somewhat slow down, the process? Absolutely. Was it worth it? Absolutely. The Work

Comp Administrator (who testified as neutral) clearly noted in his testimony that the Court would be inclusive in seeking input from all interested parties in the process of adopting EBM guidelines. So consider this a non-issue.

- (Orthopedic Surgeon) **Nebraska doctors would be required to pay for subscription to the guidelines and for education on how to use it** - That is likely true, but Texas has a much broader base of prescribers and injured workers and cost was not an argument that I heard for being opposed to the drug formulary. While important, better treatment trumps cost.
- (Trial lawyer) **Takes away decision making capability of doctor** - Not true. A properly constructed drug formulary, with the companion EBM guidelines, actually enhances the decision-making by prescribers because now they have access to all of the clinical studies, comparison of treatment options, and recommendations that will assist in making those decisions. In the case of a drug formulary, if the prescriber really feels that an excluded drug is the right treatment for this patient at this time, then they should be given the opportunity to prove why with rigorous and scientific and objective - not anecdotal - studies and experiences. If they can't prove that point, complying with the EBM recommendations (by choosing an included drug or a non-pharma option) is likely the right thing for the injured worker.
- (Trial lawyer) **The need for a drug formulary sends a message that either the doctor is incompetent or not acting in the best interests of the patient** - I don't disagree, to a point. We wouldn't have an epidemic of both medical and non-medical use of "pain pills" if prescribers were doing the right thing every time. Through PRIUM's services, I've seen thousands of claims in many states since 2003 and a large percentage of prescribers are appreciative of education on less dangerous / more effective treatment options. And, once informed of those options, they work actively to move the patient to an agreed-upon alternative. I have seen hundreds of injured workers who, when their drug regimen was reduced and/or removed, actually regained function and quality of life. I know of several phone calls directly from injured workers who have thanked us for our role in changing their dangerous drug regimen. That tells me prescribers weren't all incompetent, or consciously acting against the best interests of the patient, but just lacked full education as to the available options. This straw-man argument lacks the nuance of this complicated problem.
- (Trial lawyer) **The drug formulary would require "evidence-based medicine" that currently does not exist in Nebraska** - That is a valid point. But the applicable EBM would be determined during the rule-making process. By involving all stakeholders in that discussion, it would be a vetted (and hopefully consensus based) decision.
- (Trial lawyer) **California has been trying for two years to pass a drug formulary** - Inaccurate and intentionally misleading. California's drug formulary will be implemented by July 1, 2017. The rule-making process is well underway. I was part of the dialogue over the Summer (the content will remain confidential) with the various stakeholders and I know the intention of not only the Administration but also of legislators and doctors and Labor and a

large list of other stakeholders. It was, and is, towards providing the best clinical interests of the injured workers.

There were some questions offered by the Senators throughout the hearing that are also of interest:

- (Sen. Howard) **Does the Work Comp Court have the expertise to create a drug formulary?** No. But in the classic "buy vs. build" scenario, "buying" EBM that has a built-in drug list renders the Court's level of expertise a moot point.
- (Sen. Howard) **Would the drug formulary completely remove the ability to prescribe OxyContin?** No, only when its use does not match EBM. For chronic pain, that is the vast majority of the time.
- (Sen. Crawford) **How does a drug formulary battle addiction and trafficking?** This is an excellent question, one that I would have liked to address directly with the Senators. A Work Comp drug formulary will only directly impact injured workers. For those that have developed a dependence or addiction due to their treatment, a drug formulary can have (and, in my opinion, already has had in other states) a significant positive impact. That is a very good thing. However, Work Comp is only a small fraction of the overall healthcare industry. So can a Work Comp drug formulary have an impact on other patients? There is no empirical evidence to back this up, but my common sense supposition is that when prescribing behavior is changed due to EBM being introduced it will impact <u>all</u> patients (regardless of payer) who are seen by that prescriber. At some point, whether Work Comp makes up 1% or 100% of a prescriber's practice, the status quo has been changed by consideration of other options being required. So ... Will a Work Comp drug formulary fix our Rx epidemic? *Absolutely No*. Can it make a dent in the problem as part of a larger societal strategy? *Absolutely Yes*. **Don't let the perfect be the enemy of the good.**
- (Sen. Crawford) **Don't carriers already have their own formularies?**Yes. More accurately stated, a PBM has a formulary that a carrier/TPA employs. But since each PBM's formulary is unique and not tied to a statutory mandate, their value is based on voluntary compliance by the prescriber. There is considerable value to a PBM formulary. But there is a broader impact if the state mandates a single standard for all carriers and prescribers in the system.
- (Sen. Howard) **How would this solve doctor shopping that a better PDMP might better address?** A drug formulary would not be as effective in combating doctor shopping or pharmacy hopping as a PDMP, which is why I'm firmly in support of Sen. Howard's LB 471 to enhance Nebraska's PDMP.

I am a proponent of drug formularies as **<u>part</u>** of the toolset to address our prescription drug epidemic. A drug formulary is not **<u>the</u>** solution but **<u>a</u>** solution. Along with a robust PDMP, state-mandated treatment guidelines, opioid treatment agreements, urine drug testing, and better education of prescribers and patients, it can be a tremendous asset. *To fix this epidemic we need to utilize every single resource at our disposal.*

The final statement in my testimony was that a properly constructed drug formulary creates a **"pause moment"**. For the prescriber. For the patient. For the payer. Rather than continuing the status quo, challenge it to ensure the most clinically appropriate choice is made.
I believe there is common ground for the common good, especially with the NMA and the doctor. Many of the comments were reflexive responses that I've heard as concerns while advising other states, but I'm confident they can be addressed with full collaboration and a willingness to listen. At the end of the hearing, Sen. Harr stated that the bill's language might need some additional work but that he was willing to put in the effort. As am I.

All indications are that with a short legislative session the bill will not pass. So this could have been a "dry run" for 2017. Hopefully it gets done, sooner than later. **Lives are at stake.**

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