## Webinar questions answered by presenter
## Nikki Wilson, Director, Pharmacy Product Development, Mitchell

1. **What are the current CDC Guidelines for MED Level? Pharmacies such as CVS, Walgreen's are all using different levels through our PBM.**
    a. The recommendation from the CDC is to use the lowest effective dose of opioids for the shortest duration possible, and to carefully reassess evidence of individual benefits and risks when considering increasing the daily dose above 50 MED. The CDC recommends avoiding increasing dosages to 90 morphine milligram equivalents per day and recommends considering consultation with a pain specialist if higher doses are thought to be needed. You are correct, that the MED thresholds are more of a guidance and can vary from resource to resource, but 50 and 90 are those I see most-commonly upheld by the guidelines (like ODG, ACOEM, CDC).
2. **Is tramadol an opioid?**
    a. Yes. It is a synthetic opioid that acts on both the opioid receptor and through other mechanisms to manage pain. This is where I think some of the confusion comes in from providers and others with the misconception that tramadol is "safer" than other opioids or is a non-opioid medication. Tramadol's other mechanisms of action include effects on serotonin and norepinephrine levels, similar to the way tricyclic and SNRI antidepressants work to improve pain. That being said, when used as intended at prescribed therapeutic doses, genuine physical/pharmacological dependence is rare (given the drug's relatively lower affinity for the opioid receptor vs. other opioids), but psychological dependence and abuse is not uncommon, especially in those with substance abuse history. In other words, tramadol is prone to the same abuse and diversion and carries similar risks and considerations as other opioids.
3. **You mentioned time - time with doctor, recovery time, etc. - as a major player in this. Are we seeing money as a big influence? High margin for manufacturers? Lower cost than alternative treatments for providers? Both?**
    a. I would say any and all of the above. Certainly, the incentives/payment from payors plays a role. Payors typically don't offer billing/payment for time spent educating patients on pain management, however, prescriptions are reimbursed, surgical procedures are paid, etc. So that is a piece of the puzzle in general in our healthcare system. The other aspect I think is a lack of education in the area of pain management and opioid prescribing. We are making gains in this arena I think today, but many providers do not have adequate training, if you will, on what other treatment options are available, how to dose/monitor/wean a patient on opioids. When to start opioids, when to stop. And there historically haven't been a lot of incentives or requirements that would promote such training. Although we are seeing a shift in that direction.
4. **I have heard that tramadol is not an opioid where the patient or doctor needs to worry about addiction or increasing tolerance. Is that true?**
    a. See response to question 2.
5. **Aside from telling if a patient is taking opioid medication, can drug testing determine if a person is taking their full dose (aka, taking 1 pill versus 8 pills) of medication? I have a case with a claimant on very high doses of narcotics and we can't help but wonder if she is selling some of her pills while taking a smaller amount than prescribed. Thanks.**

a. Urine drug tests can be qualitative (i.e., is the drug detected or not) or quantitative (i.e., number value associated with the level of the drug). While quantitative tests give us a bit more information, unfortunately today there is no reliable relationship between the amount of drug taken and the quantity of drug or drug metabolite found in the test sample. Results typically don't prove enough information to determine exposure time, dose taken, frequency of use, etc. In general, UDT result values can be affected by many variables (including drug-drug interactions, genetic variations in the patient, pharmacokinetics, drug metabolism and clearance, and possibly the clinical conditions the patient has). Using numbers alone isn't considered a good practice. In short, drug testing can be complicated, interpreting results can be difficult, and misinterpretation is not uncommon. Consulting with lab analysis professionals at a reputable UDT provider may help with questionable UDT results. While UDT is an important tool in the management of patients on opioid therapy, it should not replace clinical judgement and should instead help guide clinical decision-making.

6. **Some medications are harmful for the liver, especially those who have fatty liver disease. What medications can help for chronic pain?**
    a. There are several non-opioid pain management options that do not have negative effects on the liver, with NSAIDs being one example. Checking drug metabolism and specific drug prescribing information to learn whether hepatotoxicity or liver concerns are present is advised when a patient has liver disease. Many medications will have dose adjustment recommendations within their prescribing info/package insert depending on the level and severity of the liver disease, or they will indicate if use should be avoided. I would recommend consulting the prescribing information or pursuing other routes of administration that bypass the liver (e.g., topical analgesics) if appropriate for the pain condition.
7. **How do we address the population that state they cannot take an NSAID and they are then given Opioids? It also seems many patients are being prescribed Gabapentin as a first line pain approach. Is this a new recommended protocol?**
    a. This can be tricky because it depends on why the patient indicates they cannot take an NSAID. Is the drug class contraindicated? Meaning they shouldn't take NSAIDs based on their gastrointestinal risk (defined by the guidelines as age>65 years; history of peptic ulcer, GI bleeding or perforation; concomitant use of Aspirin, corticosteroids, and/or an anticoagulant; high dose/multiple NSAID) or cardiovascular risk. Even when these risk factors are present, depending on the severity, treatment guidelines such as ODG still support NSAID use (with the addition of a protective PPI drug like omeprazole or other GI protectants where indicated), or use of a Cox-2 selective NSAID like celecoxib which minimizes GI risk. If cardiovascular risk is a concern, guidelines support the NSAID naproxen if an NSAID is used. Basically, the point is there are options, and it really is a balance of what is best for the patient and what the prescriber is willing to tackle.
    That being said, there certainly are several non-opioid pain management options available, several of which were discussed in the presentation. Most times, opioids are not the next best choice.
    b. Gabapentin for pain: Gabapentin and other anticonvulsants have become a go-to standard treatment for many types of chronic or nerve-related pain. Their use is often "off-label" (meaning the drug may not have been specifically FDA-approved for the pain condition, but we have good evidence to support use on a limited trial basis). They have not been shown to be effective in acute pain. All things considered, no drug is without risk or its own list of side effects,

and one precaution with gabapentin relates to a growing concern around its potential for abuse and central nervous system depressant effects (see FDA brief). Any decision for pharmaceutical treatment should carefully weigh these potential risks with possible benefit, and records from the prescriber should include documentation of patient's response (i.e., pain relief and improved function) as well as adverse effects). In short, benefits of use should outweigh risks of use.

8. **How do you effectively deal with a pain management MD who is prescribing, Belbucca 600 BID, gabapentin 600 QID, Norco 10-325 QID, diclofenac 75 bid, and Ibuprofen 800 TID, plus her GP has her on duloxetine, clonazepam….and her UDS are consistently negative to the breakdown meds for Belbucca, Norco, Gabapentin, and she goes ballistic when her meds are filled one minute late and claims she takes them as directed…We have questioned the MD about it and he will not respond.**
    a. I would say there are some potential red flags here. For one, the ibuprofen and diclofenac are duplicate therapy (both NSAIDs), and I would question their use together. I would question the inconsistent UDT as well (see the response to question 5 for some additional information). There can be challenges associated with testing, and UDT should be used as a tool to prompt communication and guide toward further investigation. There may be other reasons for the results, but it certainly warrants investigation. If the prescriber is not cooperative, that certainly presents a challenge. I outlined some additional recommendations in my responses to questions 19, 20, & 21 that may be helpful.
9. **How long should a methadone program last? Is it effective?**
    a. This can be variable, and results are often patient-specific. Some patients may be expected to continue medication-assisted treatment (MAT) for opioid use disorder indefinitely (months, years). Really, the length of treatment really depends on each patient's individual needs for supportive care. Research has shown that MAT (when combined with counseling and behavioral therapies) is effective in the treatment of opioid use disorders and can help some people to sustain recovery. TIP 43 is a good resource and provides additional information if you are interested.
10. **I worked at an ASC that used nerve blocks frequently to decrease the opioid use intra-op and post-op. Are there more studies being done to support this?**
    a. Yes, there are. Local anesthetics typically used in nerve blocks are one of the areas of pharmacologic developments for pain relief. One recent FDA-approval, in fact, is for a combo anesthetic-NSAID agent Zynrelef (bupivacaine/meloxicam) for post-op analgesia, and many others are following suit looking to reduce the need for opioids.
11. **Has there been any regulatory effort to specifically restrict Pain Management providers' over-prescribing (vs. General Practitioners who were the subject of last CDC Guidelines)? Thank you.**
    a. I cannot speak as much to the regulatory side of things, but guidelines and best practice prescribing (especially for opioids) applies to any prescriber. Your point is well taken in that the intent of the CDC's published opioid prescribing guidelines were largely aimed at primary care providers primarily because this is where a reported lack of education and support for sufficient training on opioid prescribing was most seen. They are not regulatory in nature, however, and are ore of a guidance document to assist providers in achieving better clinical care. In theory, Pain Management providers should be well-versed already in the risks and appropriate uses of opioids, however, the issue of over-prescribing is a concern regardless of the provider's specialty. If there are concerns with a particular prescriber's behavior, I outlined some additional recommendations in my responses to questions 19, 20, & 21 that may be helpful. There are

certain national associations, organizations, and societies out there that focus in more on specific types of pain management specialists and often they have their own guidelines (e.g., American Society of Interventional Pain Physicians), but I am not aware of any more focused federal guidance for this group today. Several states have implemented opioid prescribing limits in their juris rules and regulations in an effort to curb this issue, and we are seeing that general trend continue.

12. **What is the best/safe way to get a WC patient off of opioid use?**
    a. Support, individualized care, and frequent follow-up. The approach can vary, but typically providing weaning protocol, ensuring access to FDA-Approved assistive medications to help manage any withdrawal symptoms and/or considering MAT with buprenorphine or methadone, coordinating care among all healthcare providers and other stakeholders, considering behavioral therapies (such as cognitive behavioral therapy), evaluating and treating comorbid mental health issues, offering recovery support services (such as inpatient/outpatient detox or substance use disorder treatment) and continuing on with long-term follow-up to prevent relapse are all generally helpful for successful opioid discontinuation.
13. **What is your opinion on use of a short acting opioid in conjunction with a buprenorphine product at the same time?**
    a. It depends on the diagnosis/indication for which the buprenorphine is being used. Some buprenorphine products are FDA-approved for and indicated for pain. Buprenorphine is itself a longer-acting opioid and some providers prefer it due to its limited abuse potential compared to other opioids (resulting from the so-called "ceiling effect" where at a certain point, increasing doses of the drug do not lead to increasing opioid effects like analgesia or euphoria). In the instance of pain relief, with buprenorphine products Butrans, Belbuca, and Buprenex, it would be appropriate to provide a short-acting opioid for "breakthrough pain" (i.e., pain that comes through within the regularly-scheduled use of buprenorphine but it isn't yet time to take the next buprenorphine dose) to be used as needed. Other buprenorphine products (Subutex, Sublocade, Probuphine) and combo Buprenorphine + Naloxone (Bunavail, Cassipa, Suboxone, Zubsolv) are only FDA-approved for the treatment of opioid dependence/use disorder. In this case, it is not appropriate for the patient to be on any other opioid, including short-acting opioids.
14. **When do you think they will remove "pain" as the 5th VS?**
    a. Good question. My general understanding is that most providers and hospitals have moved away from this practice as an automatic screening for every patient. The use of the pain scale is typically now reserved more for patients presenting with a pain complaint or for whom pain control needs are anticipated (such as post-op). I would take this one step further an often promote use of a "function" scale vs. a pain scale…this helps focus the patient on improvements in function and activities of daily living as a better gauge and also can help get them out of the mindset that pain is always bad and must be eliminated.
15. **What is MD over 50 again?**
    a. MED is the abbreviation for Morphine Equivalent Dose, and it is a metric that allows for conversion of all the different potencies of opioids into one standard measure for uniform comparison. MED >50 is the daily dose of morphine equivalents where risk of overdose starts to rise considerably, and it is a mark that several treatment guidelines point to as the threshold to stay below for best practice safe prescribing. For example, the opioid prescribing guidelines from the CDC advise clinicians to use the lowest effective dose of opioids for the shortest

duration possible, and to carefully reassess evidence of individual benefits and risks when considering increasing dose above 50 MED.

16. **How long does it take to wean someone off pain meds?**
    a. As you might expect, this depends on several patient- and medication-specific factors. Weaning plans should be individualized with this in mind. The treating provider should be engaged in the process of opioid weaning, and this should be agreed upon and done under supervision from the injured worker's health care professional. The type of opioid and the patient's comorbid conditions, including substance use disorder and the need for additional treatment, may affect the rate, intensity, and duration of the taper, as well as whether the patient is best-suited for in-patient or out-patient detoxification. For example, psych conditions, risk of suicide, or a high risk of aberrant behavior could indicate that tapering in a primary care setting may be more appropriate. All of these considerations should be discussed with the provider. Some examples of general weaning schedules as recommended in the literature are to decrease the opioid at a rate of 10% per week according to the CDC or to decrease the opioid at 20-50% of the original opioid dose every week according to the US Veteran's Association. Whatever rate or method chosen for weaning, the patient should be continually evaluated at regular intervals and adjustments to the intensity of the taper should be made as needed.
17. **What are common ways doctors are using to wean patients from their Opioids**
    a. See response to question 16, and I would add that there are several opioid treatment programs out there that can offer assistance and guidance as well. If opioid use disorder is present, the patient may benefit from enrollment in one of those programs (inpatient or outpatient) to address challenges to recovery and help them discontinue opioid use safely and effectively.
18. **What do you mean by nonmedical users?**
    a. Nonmedical use as defined within the survey referenced and in general refers to use of a drug or substance beyond the scope of sound medical practice. So, for example, taking an opioid other than for its intended purpose or other than prescribed, such as using it more often than prescribed or using it outside of the oversight of a physician. An example might be a person taking their mother's old opioid prescription for a surgery she had a year ago.
19. **What are some best ways to manage a provider who continues to prescribe opioids in states that we cannot direct care?**
    a. This one can be challenging. Generally, there are several options, including but not limited to methods such as drug utilization review, peer-to-peer outreach where a physician of a similar specialty reviews the medication regimen and engages the prescriber in a clinical discussion to address opioid concerns, if your state offers it sending the opioid medication through a formal UR (utilization review) process can be helpful, engaging a clinician (such as a nurse case manager or pharmacist) to review the opioid therapy and outreach to the provider can also be helpful. Also, not to be overlooked is outreach to the patient wherever possible to discuss concerns and educate re: the risks of opioid therapy as well as other treatment options. In some instances, it may be appropriate to report a prescriber to their state's medical board if the prescribing practices are concerning enough to warrant a review of their medical license.
20. **Are there ways to report a doctor that uses continued opioid prescriptions/addiction to make sure that his patients come back every month for their script and that appears to be his business plan?**
    a. Yes, a good start would be to approach the state medical board where the prescriber is licensed. The Medical Boards typically handle licensing of medical doctors, investigating complaints,

disciplining those who violate the law, conducting physician evaluations, and can even offer support to providers who are struggling with their own addictions. The next escalation step would be to involve law enforcement where appropriate.

21. **How can any of us suggest alternatives to opioids when it is the doctor who ultimately is the one to prescribe them for the injured workers?**
    a. The prescriber is responsible for patient care, and yes, ultimately writes the prescription. However, that doesn't excuse them from or elevate them above the scope of best practice prescribing and reasonable standards of care. In the end, it will be the prescriber's decision as to how to proceed for their patient. But others can play a critical role in promoting adherence to best practices and ensuring evidence-based recommendations are followed for opioid therapy. If there is a concern about approaching the prescriber, a good option may be to engage a clinician to have those discussions. Nurse case managers, pharmacists, and even peer-to-peer reviews (physician-to-physician discussion) can be useful resources in partnering with treating providers to achieve better clinical outcomes.
22. "**Say you have a 61-year-old female that has Arthritis in both hips one knee and mid to lower back area spine is also curved. Say the person is allergic to ibuprofen as they tried 3 – 800 ml a day and it cause the person to bleed. The female has been on two 7.5 ml of Hydrocodone, 2 cyclobenzaprine 10 mg and one 15 mg of Meloxicam a day for pain management. Is there something else that they could take?"**
    a. If there is a gastrointestinal risk present, the guidelines do support options for gastroprotection if NSAIDs are going to be continued. The guidelines do support addition of a gastroprotective agent (e.g., PPI like omeprazole) along with NSAID use for patients with intermediate risk of GI events and considering a cox-2 selective NSAID (i.e., celecoxib) for patients at high risk for GI events. For example. Looking at the drug regiment listed, meloxicam is also an NSAID and carries risk of GI events. I would question whether the allergy was a true allergy to ibuprofen. A GI bleed is an adverse event that can be related to NSAID use vs. an allergy/allergic reaction to the medication. That being said, there are alternative non-opioid medications other than NSAIDs that are indicated for the treatment of arthritis and working with the prescriber to find an appropriate clinical choice would be a good next step.
23. **I have a claimant that was on opioid pain meds for close to 18 months. His pain management doctor is weaning him off the meds and it is going on 2 years that this has been going on. Does this seem excessive?**
    a. That does seem inconsistent with the standard practice. It would cause me to question what in particular is delaying the discontinuation. Is it that the goal of waning has changed? Has the prescriber determined the goal was simply to reach a safer lower dose? Or was the goal stopping opioids entirely? Has the patient experienced setbacks or might he/she benefit from more frequent support in the weaning process? Does the patient meet criteria for opioid use disorder? In general, the longer the patient has taken an opioid and the higher the dose, the more challenging they can be to wean, especially in the presences of psychological or substance use disorder (SUD). While the weaning protocol should be individualized for every patient, a general slow taper for patients that have taken opioids for longer than a year and have not evidence of SUD is to start with an initial taper of 10% dose reduction every 2 to 4 weeks, then reduction of 5% once a dose of 1/3 the initial dose is reached. An even slower general reduction schedule supported by the guidelines recommends decreasing the opioid dose 2-10% every 4- to 8-weeks. Depending on the starting dose and any other complications, overall weaning can

take months, but I am surprised that the tapering process exceeds the initial treatment duration. I would look for more information from the provider.

24. **Can the MAT drugs be as addictive?**
    a. While the medications commonly prescribed for MAT are themselves opioids (methadone and buprenorphine) and therefore do carry the same or similar risks of other opioid medications inherently, when used properly as part of an overall treatment program, the risk is minimized. Research has shown that the use of these medications in combination with counseling and behavioral therapy is an effective treatment option for opioid use disorders and can help sustain recovery. Both national guidelines such as the CDC and the workers' comp-specific ODG recommend the use of medication-assisted therapy using methadone or buprenorphine where appropriate.
25. **Do you foresee a more relaxed approached to pain management with opioids versus the broad brushed approach by physicians at this time?**
    a. I'm not sure I understand this question, so I took my best stab at it. I think what this is getting at is whether or not I foresee physicians being more selective about how and when they are using opioids for the treatment of pain. And I think the answer to that is yes. Education, state and federal regulations and guidance, and prescribing guidelines and protocols are all pointing to the drive for use of alternative options for pain, reducing or eliminating opioid use, and addressing the bigger picture when it comes to clinical care (biopsychosocial model).
26. **Have you ever seen an 80ish hour "Functional Restoration Program" ever actually help?**
    a. I don't have a lot of insight into specific case examples, but in general, the success of the program depends on several factors. Could an 80-hour FRP program be helpful for some patients? Yes, depending on the patient and goals of treatment as well as the quality of the program and fit for the indication being treated.
27. **Do you see more doctors now prescribing cannabis/cannabinoids compared to opioids?**
    a. I have not seen this in practice. There is growing interest in the area of medicinal use of cannabis and related products, but as a medical community I still feel the general consensus is that we do not have enough clinical evidence or established standards of care/production/safety and efficacy profile to support broadscale use and recommendations of this therapy as a general practice.
28. **Is cannabis used for WC injuries today in any state?**
    a. Yes, although challenges abound, including practical hurdles such as billing/banking/lack of NDC identifiers/treatment guidelines. I'd have to defer to our legal experts for the most accurate information on this one as they track these trends more closely when it comes to juris rules and reimbursement, but I do know that some states have adopted juris rules that address reimbursement for cannabis. To my knowledge as of August 2017, at least five states (Connecticut, Main, Minnesota, New Jersey, and New Mexico) had found that medical marijuana is a permissible workers' compensation treatment that requires insurer reimbursement (with CT and ME cases going through appeal), and I believe New Mexico even addresses reimbursement within their fee schedule.
29. **What about opioid medication education during the initial phase of the injury with the worker?**
    a. Early intervention and education are a critical piece of preventing adverse outcomes with opioids. I would always strongly encourage this wherever possible, and work with the patient and provider to make every attempt to limit the duration and dose of any opioid therapy, as supported by the guidelines.