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Understanding the



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Opioids and Professional Liability

A Word from ProAssurance Chief Marketing Officer, Jeff Bowlby

Opioids are a constant topic in today's news, with multiple states enacting emergency declarations to deal with the fallout. Your clients also face the liabilities associated with opioid use every day.

One in five healthcare leaders has stated the opioid epidemic is impacting their ability to serve their patients. Guidelines for prescribing opioids and treating users are becoming increasingly

strict, leaving some physicians to wonder how to assist chronic pain patients. Further, physicians are increasingly finding themselves accused of malpractice for prescribing opioids to a patient years ago who later became addicted.



Americans die from the opioid crisis every day.

As the ramifications of opioid prescribing continue to take shape, we must stand at the ready to address the questions and concerns of our clients. In this issue we will look at potential litigation trends, the workers' compensation industry, and statistics regarding how these impact physicians. There are also bright spots of hope, including tools which ProAssurance provides to help physicians take care when prescribing opioids. Our staff at Medmarc also reveals how those within the healthcare industry are developing tools and technology that make pain management safer.

If you have clients who are directly impacted by opioid prescribing concerns, please reach out to learn more about the resources ProAssurance has available.

Thank you! 🌢



What is Legitimate Medical Purpose?

by John Bowman, CEO of Sure Med Compliance

If your clients have concerns about opioid prescriptions, chances are you've heard them discuss "Legitimate Medical Purpose." The words "legitimate" and "medical" may seem redundant and you might assume that the meaning of that phrase is straightforward and unworthy of consideration. If so, consider that most DEA cases against physicians contain the phrases "in the usual course of business" and "legitimate medical purpose." Both are not simply inconsequential phrases, but rather standards that a physician will be measured by if they stand before a judge or jury.

A brief examination of case law helps paint a better picture of how these standards are interpreted and loosely defined. According to the most recent DEA Cases Against Physicians (updated 2017), the term, "in the usual course of business" is often associated with cases in which a physician was selling prescriptions or medications to patients. These cases typically involved undercover DEA agents or informants posing as patients and making purchases from the doctor. It should seem clear that selling prescriptions or controlled substances to

As your physician clients are being increasingly scrutinized for establishing legitimate medical purpose in their evaluation of patients, there are several points to carefully document.

- Well established treatment goals
 - > Patient educated on and agreed to
 - > Reasonable/achievable
 - > Specific to each patient's Activities of Daily Living (ADLs)
 - > Bad documentation: "Improve ADLs," "Reduce Pain"
 - Good documentation: "Allow patient to have a minimum of 6 hours of uninterrupted sleep and perform moderate exercise for 30 minutes, 3 days a week. Patient educated on treatment goals and agrees to plan."
- Patient-specific documentation (no generic notes)
 - > Bad documentation: "ADLs Normal"
 - Good documentation: "Good improvement in ADLs. Patient able to achieve minimum of 6 hours of uninterrupted sleep and perform moderate exercise for 30 minutes, 3 days a week."
 - > Document tapering goals and success
 - Bad documentation: "Patient being tapered"
 - Good documentation: "Tapering Xanax with goal for discontinuation by 12/23/2018"
 - Bad documentation: "Instructed patient to stop taking benzodiazepine"
 - Good documentation: "Instructed patient to taper and discontinue Xanax from physiatrist by 12/23/2018 or I will begin tapering and discontinuing opioid. Will confirm with UDT."
 - > Document aberrant behavior and patient explanation
 - Bad documentation: "Inconsistent UDT"
 - Good documentation: "Inconsistent for prescribed medication/ Norco. Patient said they ran out a few days early due to taking more than instructed. Patient was told to take only as instructed and if they begin running out early again, to call our office when they have a week of medication left. Will perform pill count and UDT."

patients is illegal and carries with it a high level of risk.

Understanding the phrase "legitimate medical purpose," however, is a bit more complicated. This phrase is also used in most cases against physicians but is not defined by the Department of Justice and only vaguely defined by individual state medical licensing boards. Upon extensive review of case law, several data points commonly involved in the interpretation of legitimate medical purpose can be noticed. These data points are usually invoked during civil and criminal cases involving over or mis-prescribing of opioids and other controlled substances. Data points like "physical exam," "misuse risk screening," and "benefit of therapy" are just some of over 20 unique pieces of data that should be considered, assessed, and documented prior to initiating opioid therapy and reevaluated each time therapy is continued.

While no doctor can ever fully eliminate risk when prescribing opioids, understanding what is being looked at by regulators, attorneys, prosecutors, and medical licensing boards and understanding how legitimate medical purpose is being interpreted—can greatly reduce the chances of being found guilty of improper prescribing.

These reminders can act as a resource for your clients. Physicians can also gain assistance with proper documentation of opioid prescriptions through the Sure Med Compliance system.



The FDA has already approved 200 devices related to the treatment of pain in the past few years. In August 2018 the FDA also awarded a research contract to the National Academies of Sciences, Engineering, and Medicine to develop evidence-based guidelines for opioid analgesics.

> Did a colleague forward you this newsletter?

Let us know if you would like to be added to the ProVisions email list.

FDA, Device Makers Respond to Opioid Crisis

Makers of opioid analgesics have found themselves under intense scrutiny—thanks to the backlash over the opioid epidemic, which by some accounts affects more than 11 million Americans. Congress continues to provide funds to respond to the crisis, and U.S. government agencies have also pitched in. As one might expect, the Food and Drug Administration (FDA) has been particularly active, accelerating regulatory review of any devices that seem likely to help thwart the epidemic.

Seeking Innovation

The agency launched The FDA Innovation Challenge: Devices to Prevent and Treat Opioid Disorder (the Challenge) to encourage makers of therapeutic and diagnostic devices to develop medical devices to prevent and treat opioid disorder in May 2018. Its objective was to spur creation of therapeutic and diagnostic devices, including digital devices, to combat the crisis. The Challenge sought applications through September 2018 and winners will be announced later this month. The winning applications will be reviewed under the Breakthrough Devices program. This program accelerates review of products that address unmet needs and/or pressing public health concerns, helping them move quickly through the FDA premarket review process.

Devices for Pain Management Already on Market

One new innovation is last month's announcement by Stimwave Technologies of Pompano Beach, Florida for the WaveCrest digital app for Apple's iPhone and Apple Watch devices. It will allow users to control the Freedom spinal cord stimulator for pain relief, a device that eliminates the need for pharmacological approaches.

In addition, drug makers are working on advanced pharmaceutical approaches that sidestep the problems seen with traditional opioid analgesics. One of the novel drug solutions directed to this ambition is VVZ-149, which is in trial for postoperative pain for patients undergoing total hip arthroplasty. This agent is a dual agonist for both glycine transporter 2 and the 5HT2A receptor. The FDA granted this product a fast-track designation, which its sponsor, Seoul-based Vivozon, Inc., announced earlier this month.

AdvaMed: Awareness of Devices is Critical

The trade associations have voiced their concerns about the crisis, including Scott Whitaker, President of the Advanced Medical Technology Association. Whitaker said in a February 6, 2018 blog at the association's website that medical technology offers a number of responses to the epidemic. He cited an AdvaMed white paper published the previous day that lists technologies that can treat pain and avoid the problems associated with orally administered analgesics. Examples include implantable intraspinal drug infusion pumps and peripheral and spinal nerve stimulation devices.

The AdvaMed paper also points to digital technology that can help manage medication dosing and timing, as well as containers that prohibit access to the drug after the prescribed period of use has elapsed. Whitaker said that given that 59,000 Americans died in 2016 of drug overdoses, "it is imperative that we educate people about the existence of innovative technology solutions, and make physicians aware that they can prescribe them as an alternative to opioids."

More to Come

In February 2018 Congress authorized \$6 billion in funding over two years for the opioid crisis. This is in addition to the \$1 billion added to federal spending for this purpose as encoded in the 21st Century Cures Act. On October 24, 2018 President Trump signed into law the Support for Patients and Communities Act also known as the Opioid Crisis Response Act of 2018. Despite these actions, the epidemic is far from contained. Given the toll the crisis continues to impose, the government's continued interest in products that address the opioid crisis seems assured.





million Americans have an opioid use disorder.

In terms of what's killing Americans, opioid poisoning outnumbers car crashes and guns. —*Michelle Mello, Stanford University*

Opioids and Lawsuits: Are Physicians at Risk?

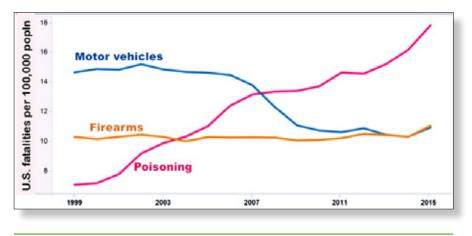
Two Stanford University professors, Michelle Mello and Nora Freeman Engstrom—experts in health law and tort law/complex litigation respectively touched on this topic as part of larger discussion focused on manufacturers and retailers, "Can Lawsuits Curb the Opioid Crisis?"

Here are some key takeaways:

- Although lawsuits against physicians who are not running "pill mills" are relatively rare, this may change.
- Inappropriate prescription of an opioid, prescription of an excessive dose, or failure to monitor a patient for dependency can be considered a violation of the standard of care.
- A Missouri appeals court upheld a \$16.7 million damage award, noting "The standard of care requires all healthcare providers to have a medication management system in place to make sure patients do not receive too many opioids."
- The same court noted physicians have to weigh the risk opioids present, "prescribe the lowest effective dose for the shortest amount of time," and assess patients for dependency symptoms.

Mello acknowledges the difficult tightrope physicians walk as they do the right thing. Now that many physicians have relied too heavily on opioids, the pendulum may swing too far the other way, causing physicians to withhold opioids from those who truly need them.

ProAssurance supports your clients, our insureds, with risk management and claims guidance. Please encourage your clients to contact ProAssurance with their questions and concerns. They can reach out to our Risk Resource Advisors at 844.223.9648 or RiskAdvisor@ProAssurance.com. Or, they can contact our Claims team at 877.778.2524 or ClaimsIntake@ProAssurance.com. We also encourage ProAssurance insureds to take advantage of the Sure Med Compliance free trial and discounted rates mentioned elsewhere in this issue.





This issue's Marketing Materials section features the Sure Med point of sale piece. We are happy to ship you a supply or answer any questions about the program at AskMarketing@ProAssurance. com. Thanks for all you do to represent ProAssurance.

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THE HOMEPAGE

Anatomy of a Multichannel Affiliate Marketing Campaign

by Steve Dapkus, Vice President, Marketing

Marketers, including your agency, have multiple channels to deliver a message. You also partner with third parties, including ProAssurance, to serve clients. In September 2018, both of those things were true for ProAssurance and Sure Med Compliance (Sure Med), an opioid prescriber's risk management software system. This month's Homepage shares the annotated playbook from our multichannel marcom (marketing communications) campaign in case it sparks an idea or two for your own future marketing plans.

The Channels

Email: Every ProAssurance insured received an email explaining the Sure Med offer at a high level with a call to action of starting a free trial. We sent the initial emails in small batches, only 100 recipients, and gradually increased to groups of thousands as we tweaked the message. We A/B tested subject lines in the early rounds, switching the larger batches to use the ones with high open rates.

Social: There's no cost to these efforts which publicly demonstrate your commitment to affiliates and others. Social media posts also become part of your organization's persistent online record. Future visitors to your Twitter page will see the program as part of your larger story as they scroll.

Press Release: Press releases are good for a couple of things. They have a level of seriousness and credibility that a company's self-serving sales webpage cannot match. Keywords may trigger automated actions like Google Alerts to notify people with related interests. And, you can use press releases to anchor "calls to action" on web pages or social media posts.

Point of Sale: We created a co-branded point of sale flyer for agents to share the information in the non-digital world. As a print piece, it can ride along in other mailers, be distributed at a tradeshow, etc.

Presentations Live and/or via Webinar: Sure Med CEO and founder, John Bowman, is on our short list for building meeting agendas to tell the story directly. John has presented to the ProAssurance Sales VPs, and the Alabama and Florida sales teams. He's happy to be present to you or be added to your group meeting agendas or conference speaking/panels for your industry contacts.

Web News/Page: The sales conversion page lives on the Sure Med website, but we created ProAssurance.com/SureMedCompliance and a separate newsfeed item. Our search engine directs traffic for explicit keywords ("Sure Med," "SureMed") and related searches such

as "opioid crisis" or "opioid resources."

This Very Newsletter: Two months ago the November *ProVisions* theme issue was going to be about social media. ProAssurance already had online seminars on opioid prescribing and many internal meetings featuring "impact of opioids" or "are opioid the next mass tort" panels. The Sure Med program helped us realize we had critical mass, so we switched the focus.

Agent Bulletins: We know that when we communicate directly with our insureds it means we are also communicating directly with your clients. Part of treating you fairly means sending you an agent bulletin outlining our communication about the program. You received it on September 6 and you can see it on our Agent Bulletins page.





As always, our Risk Resource Advisors enjoy hearing from you. Please feel free to contact us at RiskAdvisor@ ProAssurance.com or 844.223.9648.

KEEPING CONTENT CURRENT

ProAssurance Marketing Materials

Email AskMarketing@ProAssurance.com to order copies of the following new or updated communication materials:

- Sure Med Compliance Flyer
- A.M. Best Ratings Report
- MPL Policyholder Contact Card

You can access these and many other communication materials within our Secure Services Portal. Sign in at ProAssurance.com and select "Marketing Print Materials" from under the "Agent" menu.

SPOTLIGHT ON RISK RESOURCE Resources Regarding Opioid Crisis for Insureds

by Kathi Burton, MS, HRM, FASHRM, Regional Manager, Senior Risk Resource Advisor

Greetings Agents! ProAssurance Risk Resource Department has resources designed to meet our insureds' risk management needs regarding the opioid crisis.

Online seminar: Basic Principles and Advanced Concepts in Pain Management

For many patients, pain is an isolated and temporary condition that can be treated and relieved. Other patients experience chronic pain which can not only be debilitating and complex to treat, but may also lead to stress, anxiety, depression, and addiction. In this presentation, Dr. Daniel Doleys, PhD, reviews the basic principles of pain and explores advanced concepts related to chronic pain management.

Online seminar: Pain, Opioids, and Risk Management

According to the Centers for Disease Control and Prevention, the U.S. is in the midst of an epidemic of drug overdose (poisoning) deaths. Since 2000, the rate of deaths from drug overdoses has increased 137 percent, including a 200 percent increase in the rate of overdose deaths involving opioids (opioid pain relievers and heroin). Responsible opioid prescribing is an important part of any medical practice. This activity is designed to address the assessment, treatment options, and safe opioid prescribing practices for treating chronic pain patients.

As with other online courses, physicians may qualify for CME and premium credit by completing these one-hour courses and successfully passing the posttest. (Premium credits are applied at policy renewal, subject to policy terms and conditions and approval by each state's department of insurance.) For more information on available seminars, visit ProAssurance.com/Seminars.

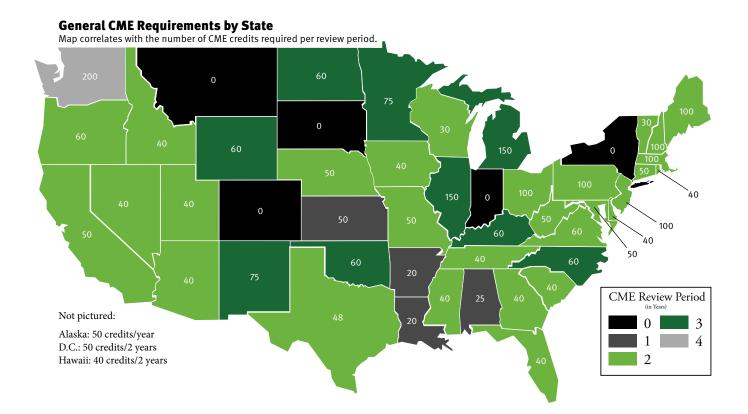
Two Minutes: What's the Risk? The Drug Seeking Patient

It can be difficult to determine whether a patient is seeking unnecessary medication or has legitimate pain management issues. In "The Drug Seeking Patient," Dr. Greg Jackson provides tips to help physicians distinguish between the two.

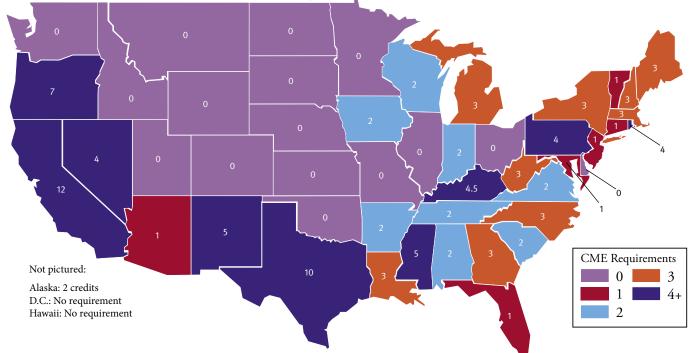
Access the ProAssurance "What's the Risk?" video series on our website or the Risk Resource YouTube channel.

Opioid Prescriber CME Requirements by State

Each state has its own specific requirements for opioid prescriber education and compliance. Although ProAssurance physician insureds can earn CME credits for successful completion of our online seminars, our seminars were not developed with state-specific opioid licensing requirements in mind and may not qualify.



Opioid/Pain Management CME Requirements by State







Learn how one worker overcame opioids through Eastern's ecovery' programs and our partnership with Paradigm.



A ProAssurance company, Eastern is a best-in-class workers' compensation provider licensed in 43 states.

Visit **EasternAlliance.com** for an office near you.

¹ Overdose Death Rates, National Institutes for Health, Revised August 2018, https://www.drugabuse.gov/ related-topics/trends-statistics/overdose-death-rates

² U.S. Prescribing Rate Maps, Centers for Disease Control and Prevention https://www.cdc.gov/ drugoverdose/maps/rxrate-maps.html

³ 2017 Drug Trend Report: Workers' Compensation by Brigette Nelson, MS, PharmD and Phil Wals, RPh, myMatrixx, https://www.mymatrixx.com/ wp-content/uploads/2018/04/myMatrixx-2017-Workers-Compensation-Drug-Trend-Report.pdf

A Workers' Comp Perspective on the Opioid Epidemic

By Suzanne Emmet, CPCU, CCEP, ARe, Senior Vice President, Claims, Eastern Alliance Insurance Group

The opioid crisis continues to make headlines. The latest Centers for Disease Control figures show 42,249 deaths from opioid overdoses in 2016.¹ Research shows that opioids are not the safe wonder drug they were purported to be, yet more than 191 million opioid prescriptions were dispensed in 2017.²

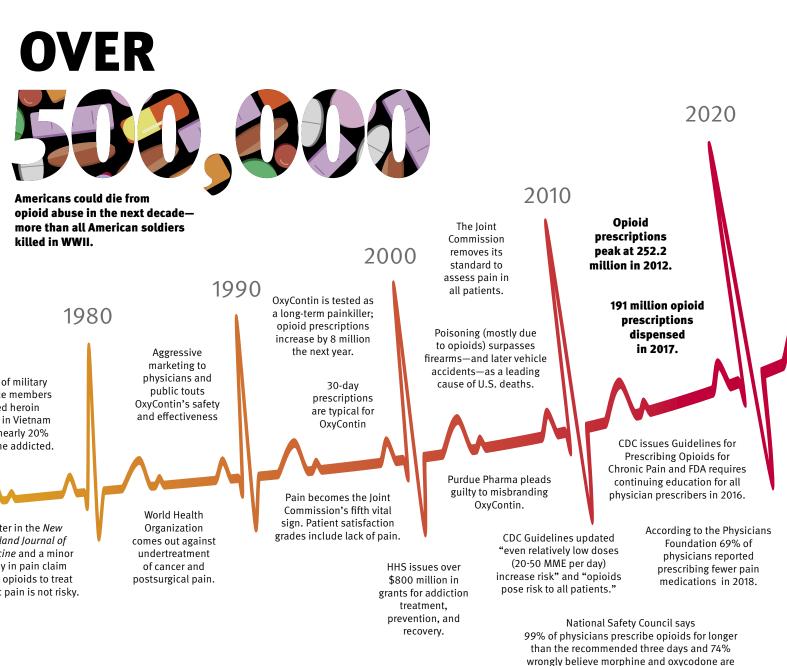
Government, healthcare, and insurers are responding, but it's an enormous ship to turn and progress is slow. Workers' compensation accounts for a small percentage of the total dollars spent on healthcare in the U.S., so it may seem that we are at the mercy of the larger healthcare market. However, there are advantages inherent in our smaller marketplace and workers' compensation benefit delivery systems. Workers' comp has produced some positive results in battling the opioid crisis over the past several years, with fewer opioids prescribed in workers' comp from 2015-2017 (-4.9%, -13.4%, and -11.9%).³

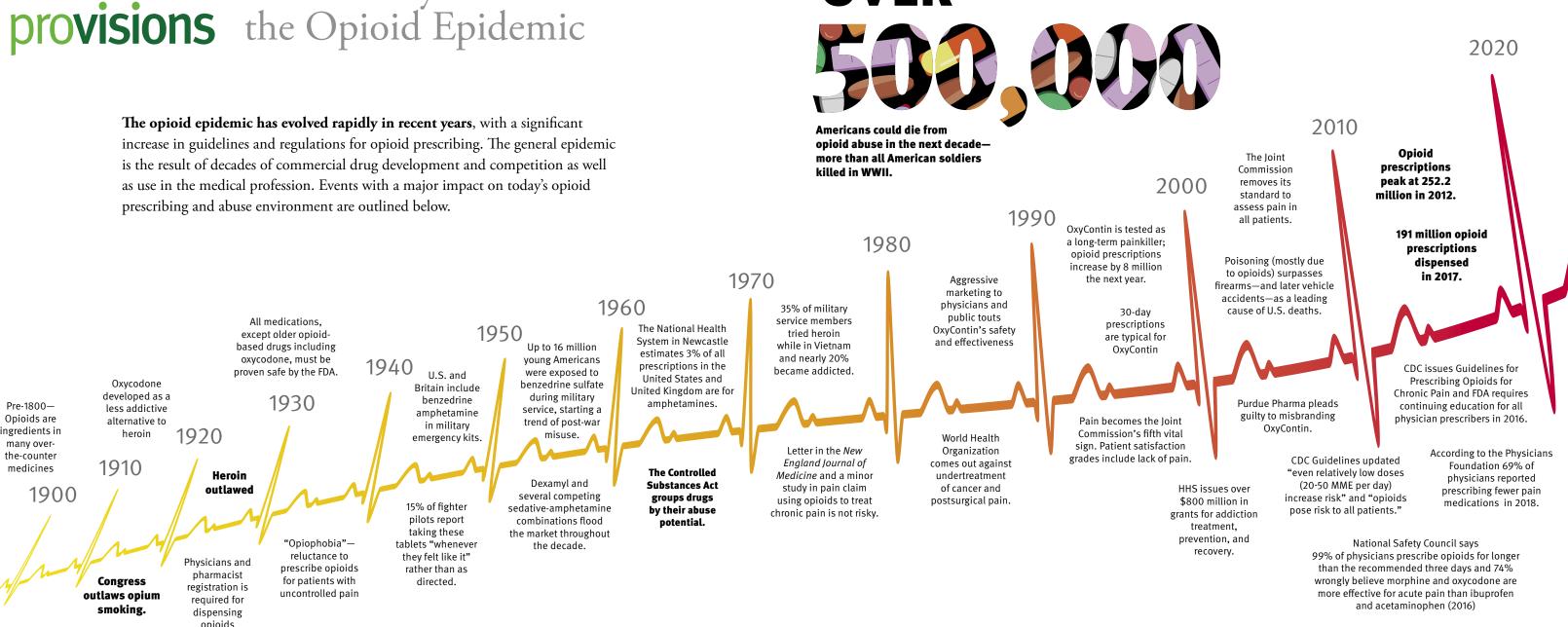
What is it about workers' compensation that has helped to achieve these successes? First, the goal of workers' compensation is to restore an injured worker's health and their ability to safely return to work after an injury. This requires that we look beyond pain control and include the employee's functional recovery in our definition of a positive outcome. Eliminating the inappropriate use of opioids is critical to helping injured workers safely return to their livelihood. Second, workers' compensation laws and regulations in many states provide carriers with effective tools to manage treatment and utilization. Evidence-based treatment guidelines and drug formularies are becoming more common, which help to ensure that injured workers receive safe and effective care. Workers' comp pharmacy benefit managers (PBMs) have also implemented some excellent programs to help stem the inappropriate use of opioids to treat work related injuries.

At Eastern we have been successful in avoiding the significant issues many carriers have experienced with opioids because of our ecovery[®] Return to Wellness claim philosophy, which takes a holistic approach and focuses on the needs of the injured worker. Our Early Intervention Nurses interview injured workers as soon as possible after the injury occurs, gathering detailed psychosocial, demographic, and medical data to proactively identify the workers who may be at risk for adverse outcomes, including opioid addiction. We can then implement strategies to provide extra support. One of the most effective strategies has been our partnership with Paradigm Outcomes and their complex pain program; it includes specialized clinical resources and a systematic care management model. Our process features direct referrals of at-risk workers to the Paradigm program. It also uses a comprehensive data analytics component that identifies emerging complex pain cases before they become problematic.

Working together, Eastern and Paradigm collaborate with the treating medical providers and the injured worker to develop a better course of treatment. This may include a tapering plan for problematic drugs, alternative pain management strategies such as cognitive behavioral therapy (CBT), and inpatient detoxification and functional restoration programs. Every injured worker is provided with a support team and an individualized, multifaceted approach to dealing with their pain and their recovery; they receive evidence-based medicine guided by experts that focus on the whole person. Early identification and effective intervention are critical for favorable outcomes and continuing to stem the tide of the opioid crisis.







Opium, heroin, and morphine addiction takes hold after the Civil War. Laudanum (opium and alcohol) is a popular cure-all.



Americans are affected by opioids

This includes additional research on long-term use of prescription opioids and misuse of these medications. Stricter standards continue to be developed for prescribing and providing access to opioids. Although U.S. drug overdose deaths had increased over four decades, the CDC reported a 2.8% decline from March 2017 to March 2018. While this is an early statistic, there is hope that this is the beginning of a new trend.

(Source - see page 11 for suggested reading.)

Today, organizations including the FDA and CDC focus their efforts on addressing opioid abuse.





Reminder: Use New Submissions Email

Please send all information regarding new business and add-on opportunities to Submissions@ ProAssurance.com. Pertinent information to

include is the legal name of the entity as well as the state of practice. If sending encrypted emails, please continue to copy your Underwriter and/or Policy Specialist. If you have questions, please call your Policy Specialist at 800.282.6242.

SALES TIPS FROM THE "OLD SCHOOL"

Affiliations: Powerful Assets

State, county, and specialty associations and societies provide invaluable insights into the thinking and interest levels of our clients and prospects. Our more engaged physicians belong to and lead these important organizations. By their very nature, these nonprofit entities mirror the issues and political direction of their physician memberships.

Old School is intimately involved in two such affiliations, both of whom exclusively endorse ProAssurance.

Yes, the most natural reason to covet an endorsement relationship is to gain favorable access to the membership for new business opportunities. But that alone is not what makes such an affiliation a powerful asset.

Recent consolidation by hospitals, private equity, and large groups in the physician space is putting financial pressures on organized medicine. The Old School reminds everyone that value is a two-way street. One must evaluate the resources required for the relationship and determine the appropriate fit for human effort and monetary resources allocated. This is never an easy process but one Old School pupils are more than equipped to handle.

Physician-oriented organizations provide unmatched insight into what issues motivate and drive the interest and active participation of the members. Two recent topics come immediately to focus: the opioid epidemic and physician burnout. Sure, numerous published articles and broadcast efforts highlight both issues. But, nothing can duplicate or replace the impact of in-person discussions and debate at society and association gatherings. In-person. Emotional. Unfiltered.

Seeing these issues illuminated in the raw is powerful. And, learning the importance of such issues firsthand through the partnership of an affiliation is an asset unmatched in understanding our market. The opioid crisis, in particular, is impacting your clients every day. They need support and someone willing to listen.

Partnership. If your affiliation is to provide truly trusted give and take, it must be a partnership committed to by both parties. In such a relationship, you will learn how your company is viewed for both better and for worse. And, the benefit of receiving the unvarnished truth of that equation is an asset to be prized.

Old School has the scars to prove that membership physicians who get to know you more intimately than just through the sales process are quite willing to let you know all—and everything—wrong with your company, its products, its services.

Knowing the "perceived truth," while painful at times, is priceless knowledge.

And here's the icing on the cake: membership administrators and physician members will frequently give you telling information and intelligence about your market place competitors. Whoa! Imagine that!

Then your organization can create new partnerships designed to further support and nurture these relationships, ultimately strengthening your business ties. See ProAssurance's most recent efforts in this regard with the relationship forged with Sure Med to combat the stresses of managing opioid prescriptions correctly.

State, county, and specialty association and society endorsing relationships are powerful assets to be prized, polished, and cared for. They require your attention. They are worth your attention. Old School suggests you give them the attention they deserve. They require your effort to create the partnership that is, in the end, more powerful than the endorsement itself.

Good luck and good selling!





Nearly 30% of surveyed workers' compensation claimants filled an opioid prescription more than 90 days after the date of injury.

11 Articles to Assist Your Knowledge

To help support your knowledge of issues in the healthcare environment, see our list of article links below. Please let us know if there are additional sources or topics you want us to monitor by emailing AskMarketing@ProAssurance.com.

- 1. Using research, best practices to fight the opioid epidemic by Dylan Fisher, Physicians Practice, March 7, 2018
- 2. EMRs are hospitals' tech-of-choice for opioid management, KLAS finds by Jessica Kim Cohen, Becker's Hospital Review, October 23, 2018
- 3. Specialists have big roles in combating the opioid crisis_by Rebecca Parker, MD, American Association for Physician Leadership News, July 23, 2018
- 4. Overdose deaths have fallen for six months. Is it temporary or a sign of a corner turned? by Andrew Joseph, STAT, October 23, 2018
- 5. Opioid crisis fast facts, CNN Library, November 5, 2018
- 6. Survey: How hospital leaders are responding to the opioid crisis by Tina Reed, Fierce Healthcare, October 29, 2018
- 7. Opioid use often persists in workers' compensation claimants, Neurology Advisor, November 5, 2018
- 8. FDA launches medical device innovation challenge to combat opioid crisis by Chris Newmarker, Drug Delivery Business News, May 30, 2018
- 9. Dentists: On the front line of the opioid epidemic by Erin McHenry, University of Minnesota
- 10. Opioid Use Disorder More than Quadruples in Moms at Delivery by Molly walker, Medpage Today, August 9, 2018
- **11. CMS wants to probe opioid use at skilled nursing facilities** by Maggie Flynn, Skilled Nursing News, July 19, 2018

Because of rapid advances in the medical sciences and legal regulations, we recommend independent verification of facts. Information in this publication is current as of the date of the printing.

If any questions or concerns arise, please contact us at: TreatedFairly@ProAssurance.com. M4666

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