RED SIGNAL REPORT℠

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Claims Data Signals & Solutions to Reduce Risks and Improve Patient Safety

OPIOIDS

COVERYS®

Reduce Distractions. Improve Outcomes.®

MEDICAL LIABILITY INSURANCE • BUSINESS ANALYTICS • RISK MANAGEMENT • EDUCATION

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I. Introduction

The Red Signal Report℠ series is designed to assist healthcare organizations in identifying issues that impact risk management, patient safety, and quality outcomes. The focus of this report is on opioid-related malpractice signals to identify the major risk factors, warning signs, and safety vulnerabilities within the pain management process. Even more importantly, it addresses evidence-based risk recommendations and practice changes that can improve patient safety while reducing malpractice exposure to opioid-prescribing clinicians. The report is based on a review of five years of closed claims identifying 165 patient events involving opioid medications.

II. Executive Summary

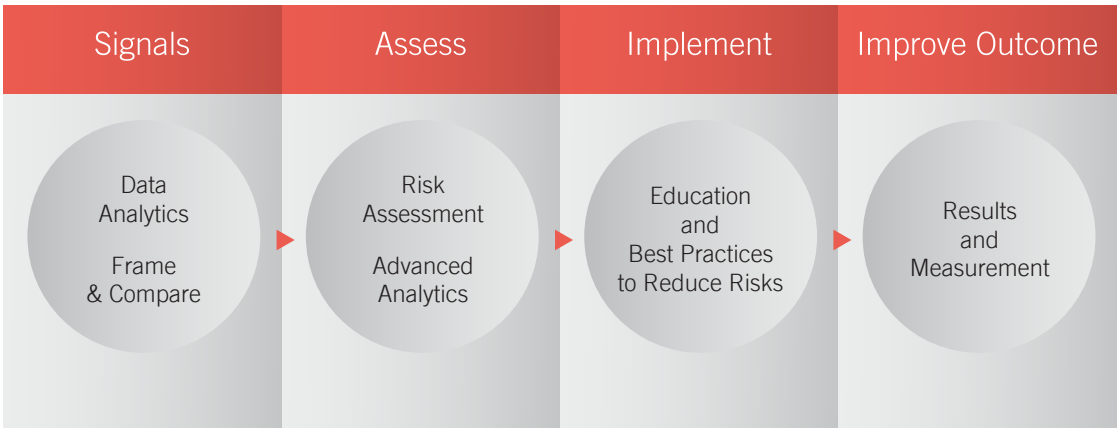
A dramatic increase in opioid use over the past several decades has led to an epidemic of addiction and high-severity injuries, including death. This growing tragedy is taking thousands of lives each year and is impacting patients, family members, and clinicians. The costs are staggering. According to the National Institute on Drug Abuse, "the total 'economic burden' of prescription opioid misuse alone in the United States" has been estimated to be $78.5 billion a year.[1]

The opioid epidemic in the United States has become pervasive throughout our communities and addressing it has proven to be very challenging. Caught in the middle of this crisis are healthcare providers. Many have been accused of prescribing practices that fuel addictions. From 1999 to 2017, the opioid epidemic in the United States contributed to the deaths of over 700,000 people; the number of opioid-related overdose deaths was six times higher in 2017 than in 1999.[2]

Coverys' Value-Based Continuum

As is the case with all Red Signal Reports, Coverys documents not only claims trends but also provides the reader with a practical roadmap including signal data, assessment tools, practice change best practices, and sample performance metrics. The following table outlines this proprietary Coverys process.

Coverys Utilizes a Value-Based Model to Improve Outcomes



Coverys analytics leverages claims data to identify and classify prominent risk signals.

Coverys Risk Management provides on-site assessment or a self-assessment tool to identify the presence of risk signals.

Med-IQ, a Coverys company, delivers education and best practice recommendations to reduce risks and improve patient safety.

Metrics can then be established to measure progress and track areas of exposure needing intervention.

III. Pain Management Process - Data Signals

The recent Dose of Insight report from Coverys, A Data-Driven Review of the State of Medication-Related Errors and Liability in American Healthcare, examined the process steps of medication management in some detail. This latest report, however, focuses on the more specific steps that relate to active pain management: screening/prescribing, dispensing/administering, monitoring/ongoing management, and tapering/discontinuance. Each step has associated risks that can contribute to opioid dependence and persistent use. Coverys malpractice events involving opioid adverse outcomes demonstrate that this process can break down at any step along the way. (See Figure 1.) In addition, more than half of the events involve errors in more than one phase of care.

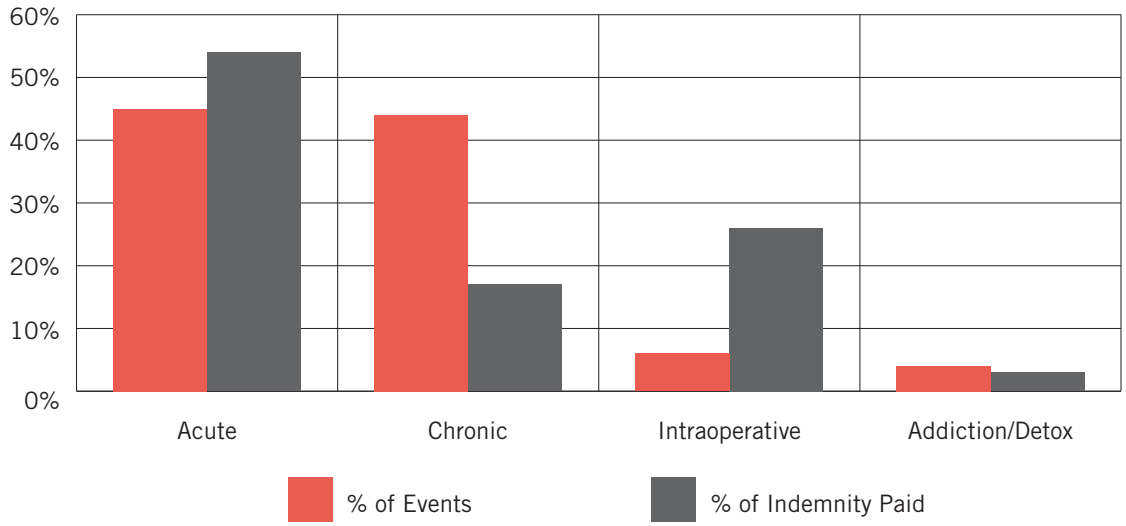
Figure 1. Pain Management Process

Selection: N=165 closed events between 2014 and 2018 involving an opioid medication

Not surprisingly, the Coverys data show that an opioid is most commonly given for acute pain. (See Figure 2.) These acute events most frequently arose from treatment rendered in inpatient hospital rooms, followed closely by treatment provided in emergency department surgical units, and physician offices. These locations account for over 80% of indemnity payments for acute events.

The second-highest driver behind opioid prescribing was found to be chronic pain. It should be noted that these cases resulted in lower indemnity payments. Over 60% of the chronic events arose from treatment provided in physician offices or outpatient clinics.

Figure 2. Reason for Pain Management

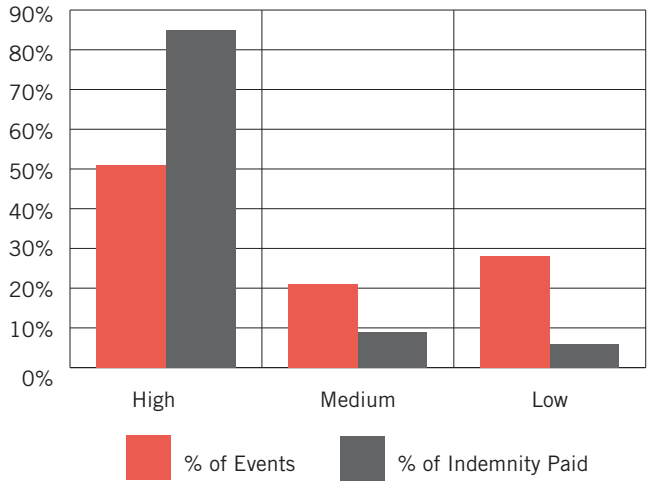


Selection: N=165 closed events between 2014 and 2018 involving an opioid medication

Injury Severity

Half of all opioid events involve a high-severity patient injury (including death). The tragic outcomes opioids have on patients are alarming and so are the associated costs. These high-severity events accounted for 85% of the indemnity payments. (See Figure 3.)

Figure 3. Injury Severity

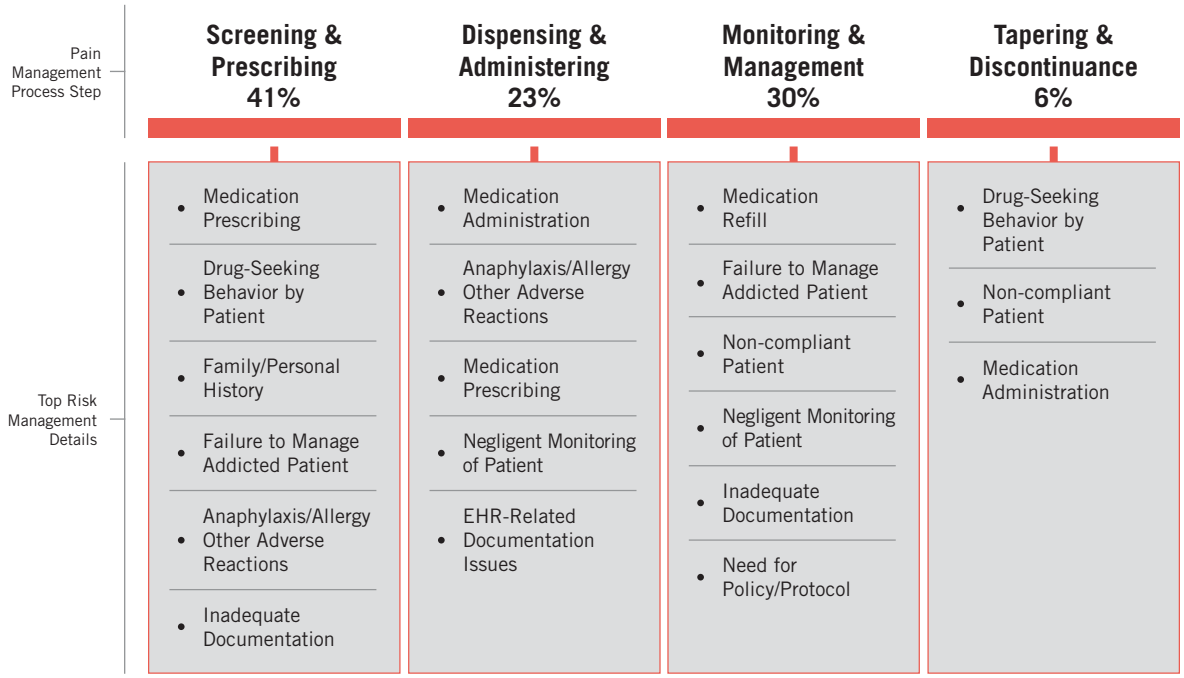


Selection: N=165 closed events between 2014 and 2018 involving an opioid medication

Risk Management Issues

Risk management issues were identified across the pain management process. Some issues spanned multiple process steps. Figure 4 below shows the top risk management issues associated with each step.

Figure 4. Percentage of Risk Management Issues



Selection: N=165 closed events between 2014 and 2018 involving an opioid medication

IV. Proactive Risk Assessment

A key step after initial examination of the data signals in this Opioid Red Signal Report is to take a proactive look at the identified risk factors and safety vulnerabilities within the pain management process of care. Performing an internal assessment to see if the identified exposures currently exist in your organization or practice can provide you with direction to prioritize process improvement initiatives. Assessment should include review of internal processes related to opioid screening and prescribing, dispensing and administration, monitoring and management, and discontinuance and prevention of drug diversion. Self-assessments will help identify organizational strengths, areas of opportunity to enhance patient care, and may reduce your potential liability. For more information on these assessment tools, Coverys policyholders should contact Risk Management at 800.225.6168 option 9.

V. Pain Management Process

While risk management recommendations specific to each step of the pain management process are addressed later in this report, the following recommendations are generally relevant to every step of the care process:

- Perform ongoing assessments of patients for risk factors and the effectiveness of the opioid therapy.
- Educate the patient on opioid side effects and, most importantly, the possibility of addiction. Before prescribing additional opioids, always check your state's prescription drug monitoring program (PDMP) database for information on the specific patient.
- Conduct additional screening and laboratory tests as indicated.
- Document patient assessments, efficacy of opioid therapy, PDMP database findings, test results, and consultations/discussions with the patient and other treating providers.

1. *Screening and Prescribing*

The highest percentage of opioid events in our study (43%) had root-cause factors pointing directly to medication screening and prescribing, and accounted for 39% of the indemnity dollars. (See Figure 1.) In this first step of the pain management process, a clinician evaluates the patient's presenting symptoms, medical history, and clinical severity in order to determine a medication type and dosage. This is the most critical step in the process and where – if close attention is not paid – overprescribing practices can sometimes begin. Coverys data show that over 50% of the patients involved in these events had either a psychiatric or substance abuse history. It is well established that the relationship between mental health disorders and opioid addiction is bi-directional. Additionally, chronic use of opioids has been linked to an increased risk for depression.[3]

Caring for patients with chronic pain that is not associated with cancer requires diligence balanced with empathy. A comprehensive discussion with the patient and family members is recommended. Such a discussion should be thorough in its scope and should include a review of the risks and benefits of each therapy under consideration. Treatment goals that reflect realistic expectations should be established with the patient's participation, and then regularly revisited and reevaluated during the course of treatment.

CASE SCENARIOS

- A patient saw a new physician for an initial office visit and was prescribed long-acting Hydrocodone. The physician was unaware that the patient was also taking Oxycodone. The patient began taking the new prescription and died two weeks later.
- A cardiovascular physician prescribed a Fentanyl patch to a patient for chronic pain, steadily increasing the dose from 50 mcg to 200 mcg over four months. The patient was found dead at home 15 days after the last increase. Experts determined that the 200 mcg dose was higher than warranted for this patient.

Risk Recommendations for Screening and Prescribing

It is important to determine whether the patient's pain is acute or chronic, and then follow the indicated practice guidelines. Before prescribing opioids to patients, they should be screened for opioid-related harm risk factors using a validated assessment tool, such as the Screener and Opioid Assessment for Patients with Pain (SOAPP). It is also important to conduct a full medication reconciliation at every patient encounter. The following recommendations have been abstracted from *Minnesota Opioid Prescribing Guidelines*, First Edition, 2018.[4]

- Check your state's PDMP whenever first prescribing and upon refilling an opioid for acute pain and before starting for chronic pain and then routinely while continuing chronic opioid analgesic therapy (COAT).
- Educate patients about using opioids to manage pain, particularly with regard to the risks of addiction. Integrate shared decision-making into all exchanges with patients. Carefully describe the risks and benefits. Repeat education routinely throughout the course of opioid therapy. Provide information regarding the safe storage and disposal of opioid medications.
- Assess the risk of pregnancy for all women of childbearing age. Avoid prescribing opioids to pregnant women. If opioids are prescribed, educate the woman about the risks to herself and the fetus. Prescribe the lowest dose for the shortest duration.
- Document the patient's presentation of pain and diminished function using an approved pain scale and objective observations (e.g., vital signs, medication history, and applicable laboratory test results) prior to prescribing opioids.
- Avoid concurrently prescribing opioids and benzodiazepines or other sedative hypnotic medications. Exercise extreme caution when prescribing opioids to patients who are already using benzodiazepines or other sedative hypnotic medications.
- Address the concomitant use of benzodiazepines or other sedative hypnotic medications for patients on COAT.
- Avoid prescribing opioids for fibromyalgia; headache (including migraine); self-limited illnesses (e.g., sore throat); and uncomplicated acute neck, back, or musculoskeletal pain.

- Exercise extreme caution when prescribing opioids to patients who have comorbid conditions that may increase the risk of the patients experiencing an adverse outcome. Such comorbid conditions include chronic obstructive pulmonary disease, congestive heart failure, obstructive sleep apnea, a history of alcohol or substance use disorder, advanced age, or renal or hepatic dysfunction.
- Consider conducting a patient urine or blood screen that is specific for opioids and illicit drugs prior to prescribing opioids.

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2. Dispensing and Administering

The second step in the pain management process of care involves dispensing and administering the prescribed opioid for the patient with acute or chronic pain. This step accounted for 23% of Coverys opioid events and resulted in 29% of the indemnity payments. (See Figure 1.) There are many checkpoints to consider when instituting long-term opioid therapy, including the initial evaluation prior to dispensing, renewal of medications without seeing the patient, and conducting a reassessment on the return follow-up visit. Throughout this step, it is important that both the pharmacist and prescribing clinician evaluate opioid dosages, especially in light of other medications the patient is taking.

CASE SCENARIOS

- A post-operative patient was admitted to the OB unit with complaints of pain following a laparoscopic vaginal hysterectomy. She was given Benadryl, Demerol, and Zofran and had an adverse reaction. The patient was found unresponsive after a cardiac arrest and was resuscitated. Documentation noted that the patient was sensitive to intravenous narcotics.
- A patient seen in the emergency department with abdominal pain was prescribed a 50 mcg Fentanyl patch and discharged. The patient was found unresponsive at home. Narcan was administered with minimal response. The patient is now wheelchair-bound with limited ambulation and mobility.

Risk Recommendations for Dispensing and Administering

The following recommendations have been adapted from a memorandum and transmittal from the Centers for Medicare & Medicaid Services.[5]

- Ensure that opioid medications are administered or dispensed only by a practitioner licensed under the appropriate state law and registered under the appropriate state and federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner.
- Require that opioid infusions are either prepared by the pharmacist or that pre-mixed infusions are purchased from a commercial vendor.
- Require the clinician to complete a double check of medication (including oral, IM, IV, & Smart Pump/PCA) with another licensed clinician before administration of narcotic medication.
- Ensure that guidelines are in place that address the timing of opioid administration and explain when opioids are "not eligible" or are "eligible for" scheduled dosing times, and that a system is in place to evaluate the administration timing policies.
- Ensure the pre-administration guidelines for opioids require an evaluation of the patient's level of pain, vital signs, last dose of opioids, and medications that can alter the effect of opioids.
- Require capnography and pulse oximetry measurement in addition to the requirements of the pre- and post-administration guidelines above when IV opioids are being administered.
- Ensure that the post-administration guidelines for opioids require an evaluation of the patient's response to the medication, vital signs, and symptoms of somnolence and respiratory depression.

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3. Monitoring and Management

The third step in the pain management process is the proactive monitoring and managing of patients on long-term opioid therapy. This step is essential to making sure that patients do not "fall through the cracks" of a busy clinic, engage in follow-up visits, and are regularly assessed to determine that the opioid therapy is still effective.

Recently, state-run PDMPs have shown promise in informing clinical practice, improving prescribing practice patterns, and protecting at-risk patients. These programs help to identify patients who are potentially abusing opioids, as well as physicians who are overprescribing them. This step of the pain management process was involved in 25% of the events and accounted for 31% of the indemnity payments.

CASE SCENARIOS

- A 45-year-old obese male patient was admitted with chronic obstructive pulmonary disease, sleep apnea, a history of psychiatric issues, alcoholism, liver cirrhosis, and acute pancreatitis. The nurse practitioner prescribed an increasing dosage of a Dilaudid intravenous infusion to 1mg/hour+ 0.3mg/6mins in the evening. Hours later, the patient was found unresponsive and could not be resuscitated.
- A 61-year-old female with a history of renal failure, chronic obstructive pulmonary disease, and sleep apnea was prescribed a 25 mcg Fentanyl patch and an increased Klonopin dose for back pain. The patient was found deceased the next day.

Risk Recommendations for Monitoring and Management

The following recommendations have been adapted from CDC Guideline for Prescribing Opioids for Chronic Pain.[6]

- Evaluate the effectiveness of opioid treatment within one to four weeks of initiating the therapy.
- Check and document the findings of the state PDMP before each patient visit and before continuing to prescribe opioids.
- Consider obtaining a pain management consult at a specified point of time in the opioid therapy.
- Consider conducting a patient urine or blood screen that is specific for opioids and illicit drugs at each patient visit and, perhaps on a random basis, prior to continuing prescribing opioids.

- Perform random pill or patch counts at each patient visit.
- Document the rationale for increasing dosages to ≥ 50 mg MME/day.
- Avoid increasing dosages to ≥ 90 mg MME/day unless carefully justified.
- Monitor patients for opioid-related adverse outcomes.

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4. Tapering and Discontinuance

This last step of the pain management process was involved in only 9% of the events. Although this frequency is relatively small, this step is crucial to ensuring that patients are slowly tapered off opioids that are no longer necessary. Tapering and discontinuance should be considered if the patient is experiencing adverse effects from the medication, if the medication is no longer effective in managing the pain, or if the underlying medical condition has improved—either from the medication or from surgical or other medical interventions.

CASE SCENARIOS

- A 39-year-old paraplegic patient was admitted with a fractured knee after having been in a motor vehicle accident. The patient was prescribed extended-release Oxycodone (80 mg, up to 3 pills daily) and Oxycodone (15 mg, up to 6 pills daily) over an extended period of time. The patient also reported taking Percocet. The patient experienced acute drug intoxication and subsequently died.
- A patient with a bipolar history presented to a clinic on numerous occasions for various complaints, including acute and chronic pain issues. The patient was seen by multiple providers who addressed his current complaints and renewed high dosages of narcotics and sedatives. The patient was found unresponsive at his home. None of the providers had formulated a care plan that included tapering or referred the patient to an addiction or pain specialist.

Risk Recommendations for Tapering and Discontinuance

For Prescribers

- Prescribe only short-acting opioids for acute pain as extended-release opioids may impact tapering. Ensure that a formal process is in place to taper and discontinue opioids and document progress on a regular basis.
- Educate patients on returning unused opioids.[5]

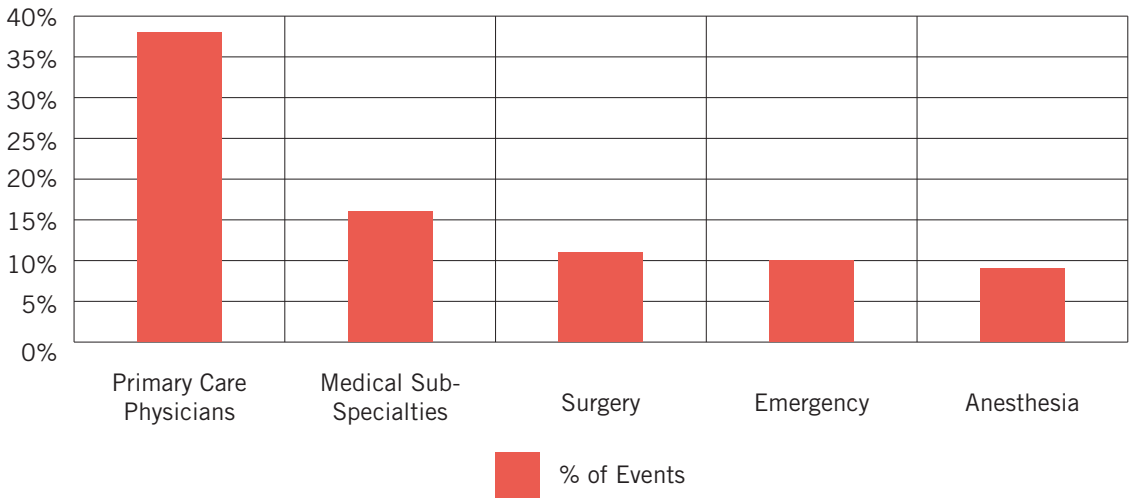
For Healthcare Facilities

- Ensure that prescribers comply with tapering and discontinuance recommendations.[7]
- Ensure that discrepancies are resolved by two authorized healthcare providers within the shift/business day in which these are discovered.[8]
- Require that access lock boxes are available in all areas where opioids may be left unattended.[8]
- Determine how to waste opioids that were opened but not used and formalize the process.[8]
- Ensure the hospital participates in a drug disposal program that complies with state and federal laws and guidelines.[6]
- Require discontinued opioids to be returned to the pharmacy within a defined time frame.

Physician Specialties

Primary care physicians were named in 38% of the Coverys opioid events. This is not surprising, given the gatekeeper role these physicians play. Specialists named in these events included medical sub-specialists (e.g., gastroenterologists, neurologists, pain management specialists), surgeons, emergency department physicians, and anesthesiologists. (See Figure 5.)

Figure 5. Physician Specialties

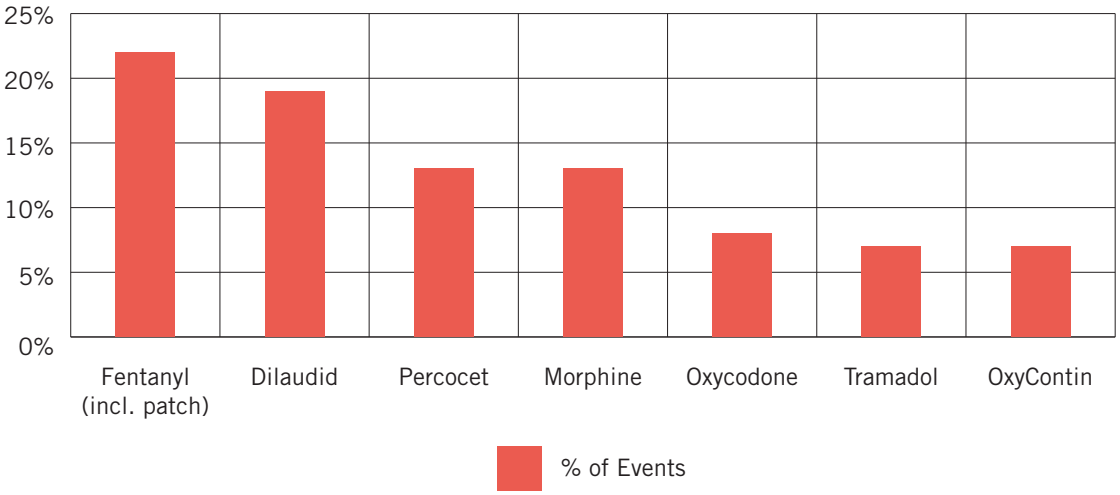


Selection: N=132 closed events between 2014 and 2018 involving an opioid medication and a named provider

Opioids and Other Medications

The top opioid drugs that were involved in these events were Fentanyl (including Fentanyl patches), Dilaudid, Percocet, and Morphine. (See Figure 6.)

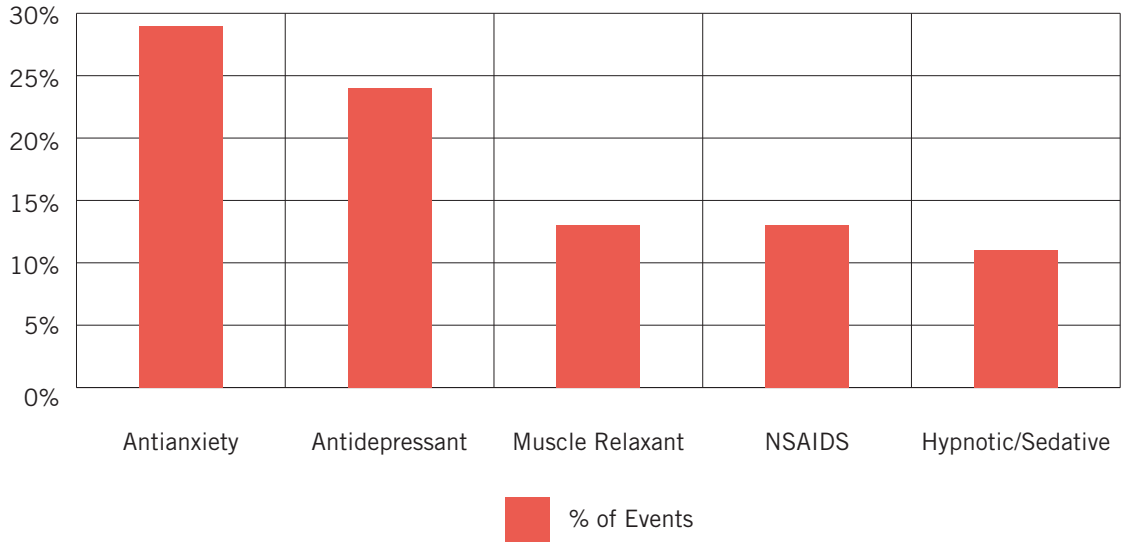
Figure 6. Opioid Medications



Selection: N=165 closed events between 2014 and 2018 involving an opioid medication

Opioids are often prescribed to patients who already have complex medication regimens. The top drug classifications that were involved along with opioids included antianxiety, antidepressant, muscle relaxant, and NSAID medications. (See Figure 7.)

Figure 7. Medications Prescribed with Opioids



Selection: N=62 closed events between 2014 and 2018 with an additional medication prescribed with an opioid

VI. Opioid Quality Measures

Quality measures related to opioid management offer providers an opportunity to reduce risk, improve patient safety, and allow for providers and practices to participate in value-based programs which can impact revenue generation.

Particular attention should be paid to the following Merit-based Incentive Payment System (MIPS) metrics:

- Annual registration in the Prescription Drug Monitoring Program.
- Consultation of Prescription Drug Monitoring Program (PDMP).
- Documentation of signed opioid treatment agreement.
- Evaluation of interview for risk of opioid misuse.
- Opioid therapy follow-up evaluation.
- Documentation of current medications in the medical record.
- Medication reconciliation post-discharge.

VII. Summary

Although many patients are able to use opioids without any issues, a national epidemic of opioid misuse is taking place and having a very significant impact on the lives of patients. The potential to become addicted—from either short-term or long-term use—is very real and can be attributed to a host of factors. The patient's personal history can play a role. The challenge for providers is to predict which patients are vulnerable to dependence and abuse. Patient education and screening for opioid-related risk factors are critical steps to take before prescribing an opioid. Providers need to have a specific plan for prescribing, monitoring, tapering, and discontinuing opioids from the outset. The Coverys claims data demonstrate the significance and costs of not properly following opioid prescribing guidelines. The risk management recommendations offered herein will provide insights to opioid-prescribing clinicians and help them ensure that their patients are managed safely and effectively.

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Additional Resources

- **CDC, Assessing Benefits and Harms of Opioid Therapy**
  https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf
- **CDC, Pocket Guide: Tapering Opioids for Chronic Pain**
  https://www.cdc.gov/drugoverdose/pdf/Clinical_Pocket_Guide_Tapering-a.pdf
- **Department of Veterans Affairs, Opioid Prescribing to High-Risk Veterans Receiving VA Purchased Care**
  https://www.va.gov/oig/pubs/vaoig-17-01846-316.pdf
- **Department of Veterans Affairs, Department of Defense,**
  VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders
  https://www.healthquality.va.gov/guidelines/MH/sud/VADoDSUDCPGRevised22216.pdf

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