OPTUM®

Addressing opioid analgesic use in workers' comp and auto no-fault

Multi-faceted efforts to reduce opioid use are underway. Formularies, treatment guidelines, limits on morphine equivalent doses (MED), and opioid quantity limits are all influencing outcomes. In recent years, the work by state regulators and legislatures throughout the country has similarly brought about change to the system.

Working together achieves healthier outcomes. The workers' comp and auto no-fault division of Optum has also been working hand-in-hand with our clients to manage pain and the corresponding use of opioid analgesics. As a result of this effort, a multi-year trend of declining opioid utilization continues. Fewer claimants are using opioid analgesics and the associated MEDs continue to follow a downward trajectory.

2.6% Change in utilization of opioid analgesics per claim

- ↓ 3.1% Number of prescriptions per claim
- ↑ 0.5% Average days' supply per prescription

6.8% MED per claim

3.3% MED per prescription

3.6 % POINTS (57.6% TO 54.0%)
Number of injured workers using opioid analgesics

0.6 % POINTS (30.8% to 30.2%)
Opioid analgesics as a percentage of total spend

1.0 % POINTS (32.6% to 31.2%)
Opioid analgesics as a percentage of total prescriptions

Opioid analgesic statistics

The number of prescriptions for opioid analgesics has escalated from around

76 million in 1991 to nearly **207 million in 2013**

80%

of all opioid analgesics dispensed in the world are dispensed in the U.S.

99%

of all hydrocodone dispensed in the world is dispensed in the U.S.

In 2010, enough prescription painkillers were prescribed to medicate every American adult

every 4 hours for 1 month

5.8 million

people have used prescription pain relievers non-medically per year

2.1 million

people aged 12 and older began using opioid analgesics for the first time in 2015

Since 2000, the rate of deaths from drug overdoses has increased

137%

25%

of all workers' compensation costs are related to opioid analgesics

91%

of patients who survive opioid overdose are prescribed more opioids

41

Americans die each day from prescription opioid overdoses

Almost 2 deaths an hour

15,000

annually

For the first time, 2016 saw a **12% decline** in opioid analgesic prescriptions, after a peak in 2012.

Opioid analgesic use in workers' comp and auto no-fault

Opioid analgesics are generally classified according to their chemical makeup, whether they are from natural, synthetic or semi-synthetic sources. They are also grouped according to the duration of action on the body, typically as short-acting (immediate-release) or long-acting (extended-release) opioid analgesics.

- A **short-acting opioid analgesic** is one with an onset of action in the body typically within 30 minutes and a duration of action from four to six hours, although these times are determined by, a large extent, the individual person's make up. Short-acting opioids may be useful in the management of acute and breakthrough pain (an acute pain exacerbation often caused by some added stimuli or change in normal routine).
- **Long-acting opioid analgesics** are designed to provide baseline pain control through slow release in the body, typically over eight hours or longer and, in the case of topical patches, up to several days (review the specific package inserts for details on particular medications). By providing baseline pain control, long-acting opioid analgesics are typically used to provide baseline pain relief to reduce the claimant's need to take multiple doses of medication per day.

The use of opioid analgesics has been under scrutiny by stakeholders throughout the system due to the thousands of overdoses and deaths stemming from opioid overuse, misuse and abuse. The Centers for Disease Control and Prevention (CDC) has released opioid use guidelines suggesting non-opioid alternative therapies as the first-line treatment along with limited opioid analgesic use, typically less than seven days of initial therapy, for most acute injuries. In addition, the CDC recommends the opioid analgesic therapy not escalate above 90 morphine milligram equivalents or greater or carefully justify a decision to titrate (adjust the dose based on claimant response) above 90 morphine milligram equivalents to achieve the desired clinical effect. Employing routine, random urine drug testing and reviewing prescription drug monitoring programs (PDMPs) to assist in managing the opioid therapy are also encouraged. Similar state-based guidelines are under review and/or in development throughout the country.

The various state versions of the legislation contain similar provisions designed to reduce the prescribing of opioid analgesics and increase awareness among healthcare providers and their patients about the risks associated with using an opioid. The common provisions include new requirements for accessing and reporting to the state PDMP, establishing treatment and documentation protocols for using opioids, providing clearer definitions for acute pain compared to chronic pain, and limiting opioid prescribing and dispensing.

The adopted legislation in each state applies to the broader healthcare market and is not specific to the prescribing of opioid analgesics in the workers' comp and auto no-fault systems. However, fully understanding the varying nuances of each state's new requirements gives adjusters, claimants and physicians more tools and insight to better address the treatment of pain and more effectively handle the utilization of opioid analgesics.

Most treatment guidelines assert the sole use of opioid analgesics for chronic pain should be avoided, especially in the case of non-cancer chronic pain. According to the Official Disability Guidelines (ODG), opioid analgesics are not recommended as first-line treatment for chronic non-cancer pain, neuropathic pain or in claimants at high risk for misuse, diversion or abuse. And while the ODG states there is some evidence for efficacy supporting the use of opioid analgesics for low back pain, their opioid analgesic use should be limited to the treatment of short-term pain. Long-term (>16 weeks) efficacy, however, is unclear and there is limited evidence supporting the use of opioid analgesics for chronic low back pain. A claimant's failure to respond to a time-limited course of opioid analgesics has led the ODG to suggest reassessment and consideration of alternative therapy. Behavioral therapy should also be evaluated, and potentially utilized, for chronic pain unrelieved by first or second-line approaches. For treatment transparency and as a form of informed consent, the use of a medication agreement between the prescriber and the claimant outlining the benefits, risks, use of opioid medications, as well as the consequences for misuse or abuse of opioid analgesics or other medications is considered a best practice. So too is adherence to prescription drug monitoring program (PDMP) protocols.

Our perspective

Even with the evidence that the use of opioid analgesics in chronic, non-cancer pain may not have the benefits once believed, in our experience, opioid analgesics do have some usefulness. There is a place in therapy for the use of opioid analgesics in managing moderate to severe acute pain, which is often attributed to accidental trauma, surgery, and occupational or recreational injury, for example:

- While certain workers' comp and auto no-fault injuries such as muscle injury or joint pain due to overuse are generally best treated using non-opioid analgesics such as non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen, opioid analgesics are considered a medication choice in claimants experiencing pain not adequately relieved by these and other first-line, non-pharmacological treatments.
- In situations where opioid analgesics are necessary to treat chronic, non-cancer pain, clinical guidelines further suggest utilization of one long-acting opioid analgesic for around-the-clock pain control. Some claimants may require the use of one short-acting opioid analgesic for breakthrough pain; however, appropriate selection and dosing of the long-acting opioid analgesic should result in minimal use of a short-acting opioid analgesic. Taking short-acting opioid analgesics often result in higher peak blood concentration levels causing more cognitive-type side effects such as drowsiness or euphoria. Since the effects of short-acting opioids only last a few hours, multiple doses per day may be needed for pain relief. This constant fluctuation of blood levels may cause further pain facilitation, erratic development of tolerance, hyperalgesia and a greater risk of addiction. Long-acting opioid analgesics, on the other hand, typically provide steady-state blood concentrations, reducing the fluctuations and thereby providing more continual and constant pain control.

In all situations, the key is making certain opioid analgesics are not only the right medication for the claimant and their injury, but also prescribed at the right time, in the right dose and for the right duration with ongoing management and monitoring to ensure clinical safety and efficacy of care. As with most medication therapy regimens, using the lowest possible dose for the shortest duration of time is a best practice in opioid therapy management. The use of non-medication therapy, including physical or occupational therapy and home exercise programs may also be an appropriate first-line therapy approach to acute injuries. Furthermore, the benefits of therapy must outweigh the risks and care must be taken to confirm opioid analgesic medications are right for the claimant and their injury, as well as prescribed in the right dose and for the right duration. To this goal, we have designed our products and services to mitigate the risks associated with opioid analgesic use. Our comprehensive utilization management strategies:

- Emphasize prevention from the first fill, because it is always more difficult to change behavior or therapy regimens after-the-fact.
- Limit utilization of long-acting opioid analgesics up to 90-days post injury for evidence-based medicine and accepted medical guidelines. This helps to reduce escalating MEDs and long-term spend.
- Utilize clinical alerts to inform claims professionals of escalating opioid utilization as well as other medication regimens not consistent with the injury or its current duration.
- Meld data with clinical expertise to provide insight into prescription use and prescribing practices, and to guide intervention efforts.
- Educate prescribers and claims professionals on the risks and benefits of using opioid analgesics through clinical letter programs, continuing education, and other tools and resources.
- Stress the importance of collaborative, goal-oriented, multidisciplinary care plans.
- Recognize the utility of PDMPs.
- Recommend the use of medication agreements, especially when a prescriber is treating chronic, non-cancer pain.
- Leverage technology to facilitate timely, secure communication and claim management.

For more information email us at **expectmore@optum.com**.

Arizona Regulation

Effective October 1, 2016

- Industrial Commission adopts ODG Chronic Pain and Opioid Treatment Guidelines.
- Urges prescribers to follow recommended ODG treatment guidelines.
- Payers to consider guidelines before denying care.
- Applies only to medical treatment or services occurring on or after effective date.
- Does not mandate preauthorization to ensure payment for reasonably required medical treatment or services.
- Prohibits payers from denying preauthorization solely because treatments are not addressed by the guidelines.

California Regulation

Effective July 28, 2016

- Adopts revised existing MTUS [medical treatment utilization schedules (treatment guidelines)] for chronic pain.
- Adopts new opioid MTUS for the utilization of opioids, which sets the recommended maximum levels of 80 MED and requires prescribers to conduct semi-annual attempts to wean patients who exceed the 80 MED dosage.

Connecticut HB 5053

Effective January 1, 2017

- Restricts the issuing of an initial prescription for an opioid analgesic to more than a seven-day supply.
- Provides exemptions for cancer treatment and at the professional judgment of the physician; however, this must be documented in the patient's file.
- Any provider who prescribes more than 72 hours of a controlled substance, other than a Schedule V non-narcotic controlled substance, shall review the state PDMP.
- Enhances reporting requirements for pharmacies to the state PDMP program from 24 hours to the "next business day".
- Requires training for municipal first responders in the utilization of naloxone, in case of an overdose, and provides protection for first responders from civil penalties.

Delaware Regulation

Effective April 1, 2017

- Limits first time prescriptions of an opioid analgesic to treat acute pain to no more than a seven-day supply unless in the prescriber's professional judgment the medical condition requires additional treatment. The prescriber shall query the state PDMP program and document the reasoning in the patient's medical record.
- For subsequent prescriptions of an opioid analgesic to treat acute pain after the first time seven-day supply, prescribers are required to first perform an appropriate evaluation of the patients' medical condition, query the state PDMP, administer a drug test (at the prescribers discretion), conduct a physical examination and obtain a signed Informed Consent Form from the patient.
- When treating a patient for chronic pain using an opioid analgesic, the prescriber shall complete all requirements indicated for using opioid analgesics to treat acute pain and shall query the PDMP at least every six months, administer a drug test at least once every six months, obtain a signed Treatment Agreement and conduct a risk assessment.
- The regulation provides certain exemptions from the acute and chronic pain treatment protocols for end-of-life, cancer and palliative care.

A **House Bill (HB)** or **Senate Bill (SB)** is a law that is initiated and passed by the legislature.
A **regulation** is developed by the Executive Branch regulatory agency, for example Workers' Compensation Commission, Insurance Department or Labor Department.

A recap of regulatory and legislative activity addressing opioid analgesics

Maine LD 1646

Effective July 28, 2016

- Imposes a seven-day prescribing limit on opioid analgesics when used to treat acute pain and a 30-day prescribing limit on opioid analgesics when used to treat chronic pain while recognizing certain medical condition and end-of-life treatment exemptions.
- Requires prescribers to check the state PDMP every 90 days when prescribing opioid analgesics and for the initial prescription of any opioid analgesic or benzodiazepine.
- Requires dispensing pharmacies to check the PDMP if the person presenting a prescription for an opioid analgesic is not a resident of Maine, is paying cash for the prescription, or the patient has not filled a prescription for an opioid analgesic or benzodiazepine in the last 12 months.
- Mandates prescribers of opioid analgesics complete at least three hours of continuing education on the subject over a two-year period.

Massachusetts HB 4056

Effective December 1, 2016

- Limits the prescribing time frame for an initial prescription of any opioid analgesic to seven days and provides exemptions for prescribers' professional judgment, cancer related care and palliative care. Exceptions should be documented in patient's medical record.
- Requires prescribers in certain circumstances to engage in addiction risk assessment of the patient and have the patient sign an opioid treatment agreement prior to the prescribing of an opioid analgesic.
- Requires the development of multi-leveled educational programs for prescribers, dispensers, first responders and educational institutions to inform impacted individuals on the dangers, risks and ways to handle opioid addiction and overdose situations.

New Hampshire Regulation

Effective January 1, 2017

- Prior to prescribing an opioid analgesic for treatment of acute pain a prescriber must conduct a physical examination of the patient, complete a board approved risk assessment tool, provide a written rationale for opioid usage and utilize a written consent form acknowledged by the patient. Prescribers are not to exceed a seven-day supply of opioid analgesics.
- Prior to prescribing an opioid analgesic for treatment of chronic pain, prescribers shall also complete the same requirements for treating acute pain and shall prescribe the lowest effective dose for a limited duration. Certain terminal illnesses are excluded from these treatment provisions.
- Prescribers must now register with the state PDMP and prior to the initial prescribing of any Schedule II, III or IV opioid(s) must query the system. When managing chronic pain, prescribers are required to query the system no less than twice a year.

New Jersey SB 3

Effective May 16, 2017

- Applies to all health care and limits an initial prescription of opioids for acute pain to a five-day supply.
- Requires use of the lowest effective dose possible.
- Prior to prescribing a Schedule II medication, the practitioner should document injured workers' non-opioid pain therapy history, including non-pharmacological treatments.
- The practitioner should document any past substance abuse history and check the Prescription Monitoring Program for opioid use history.
- For opioid use beyond five days, the practitioner should create a treatment agreement and inform the patient of the potential risks associated with long-term opioid use.

New York SB 8139

Effective July 22, 2016

- For initial treatment of acute pain, practitioners may not prescribe more than a seven-day supply of any Schedule II, III or IV opioid. Subsequent refills are subject to current prescribing limitations under law.
- Requires pharmacists to provide approved educational materials to a patient when dispensing a controlled substance. The materials must meet minimum requirements which inform the patient of the risks of using a controlled substance.
- Implements new educational training requirements for medical professionals, including physicians and pharmacists, on the practice of pain management, palliative care and addiction.

Pennsylvania HB 1699, SB 1202, SB 1368

Effective January 1, 2017

- HB 1699 limits the prescribing of opioid analgesics to seven days for patients in a hospital emergency room, urgent care facility or under observation status in a hospital. Patients being treated for cancer-related pain are exempt. The bill also requires the physician to indicate that a non-opioid analgesic medication was inappropriate for the patient before prescribing an opioid analgesic.
- SB 1202 requires all dispensers and prescribers to be registered with the state PDMP. Additionally, all prescribers must query the PMDP prior to prescribing an opioid analgesic or benzodiazepine. The bill also reduces the reporting time for dispensing pharmacies from 72 hours to close of the subsequent business day.
- SB 1368 requires development of safe opioid analgesic prescribing curriculum in Pennsylvania medical schools and continuing education programs for prescribers.

North Carolina HB 243, SB 175, Strengthen Opioid Misuse Prevention (STOP) Act

Pending gubernatorial approval

- Creates a standing-order prescription to allow governmental, non-governmental and other agencies dealing with substance abuse to access an opioid antagonist for distribution to affected members of the public.
- Allows family members or friends of persons at risk for an overdose to obtain an opioid antagonist.
- Requires a physician's assistant or nurse practitioner to consult with the supervising physician before starting a patient on a Schedule II-V drug for a time frame that is expected to exceed 30 days. It also requires on-going consultation every 90 days until the medication is no longer needed.
- Requires electronic prescribing of Schedule II-V drugs, with some limited exceptions.
- Limits an initial opioid prescription to a five-day supply for acute pain.
- Limits an initial opioid prescription for post-operative pain to seven days.
- Allows for refills of up to 30 days following the initial prescription, if the prescribing physician deems it necessary and the prescriptions are consistent with current law.
- Requires dispensers to submit data on dispensed controlled substances to the Controlled Substance Reporting System and imposes a civil penalty for failure to report.
- Requires practitioners to review the database prior to prescribing a Schedule II-V drug and to monitor the database every 90 days for patients on long-term use of a Schedule II-V drug.
- Allows third-parties, such as pharmacy benefit managers (PBM), to access the database for purposes of client case management.
- Creates a Controlled Substances Reporting System Fund to finance the on-going operation and analysis related to the reporting system.
- Exempts in-patient and in-facility care, hospice and palliative care from many of the restrictions in the legislation.

A recap of regulatory and legislative activity addressing opioid analgesics

Rhode Island HB 8224

Effective June 28, 2016

- Limits initial prescriptions of opioid analgesics for acute pain to not exceed 30 morphine milligram equivalent (MME) total daily dose per day for a maximum of 20 days, with exemptions for management of chronic pain under various medical conditions.
- Mandates registration with the state PDMP program upon initial and/or renewal of a prescriber's license for prescribing controlled substances.
- Requires prescribers to review the state PDMP before starting any opioid analgesic therapy and at least once every three months for ongoing therapy. Pharmacies shall also report the dispensing of any opioid analgesic within one business day.

Utah HB 50

Pending approval

- Limits initial prescriptions of opioid analgesics for acute pain not to exceed seven days.
- Requires providers to query the state PDMP prior to writing a prescription for a Schedule II or III opioid for the first time.

Tennessee Regulation

Effective August 28, 2016

- Adopts the first phase of their formulary treatment guidelines effective as of August 28.
- Includes the Official Disability Guidelines (ODG) Drug Appendix A, any drug excluded from the formulary would require prospective approval.
- Includes ODG treatment guidelines (opioids and chronic pain) for treating doctors.

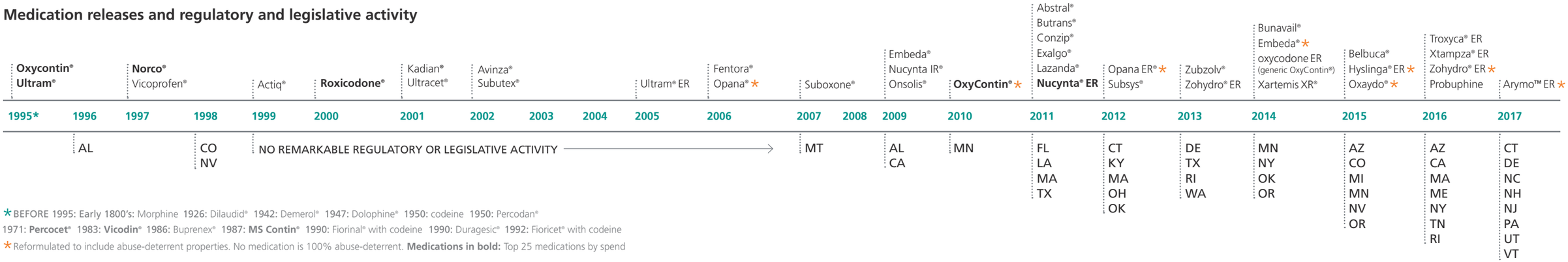
Vermont Regulation

Effective July 1, 2017

- Provides a full and clear definition of acute and chronic pain, including treatment protocols and daily morphine milligram equivalent dosage (MME) levels for both acute and chronic pain.
- Defines chronic pain as pain lasting greater than 90 days and requires the prescriber to compete a medical examination of the patient. Establishes a ceiling of 90 MME/day for treatment of chronic pain and when this level is exceeded, imparts new requirements for the possible co-prescribing of naloxone.
- Requires providers to follow universal precautions, discuss and document the risks with the patient and query the state PDMP prior to writing a prescription for a Schedule II, III or IV opioid for the first time.
- Categorizes acute pain into four specific levels of pain and establishes a ceiling of 50 MME/day for a seven-day supply of opioid analgesics.

A timeline of activity addressing opioid use in workers' comp and auto no-fault

Medication releases and regulatory and legislative activity



* BEFORE 1995: **Early 1800's:** Morphine **1926:** Dilaudid® **1942:** Demerol® **1947:** Dolophine® **1950:** codeine **1950:** Percodan® **1971: Percocet®** **1983: Vicodin®** **1986:** Buprenex® **1987: MS Contin®** **1990:** Fiorinal® with codeine **1990:** Duragesic® **1992:** Fioricet® with codeine

* Reformulated to include abuse-deterrent properties. No medication is 100% abuse-deterrent. **Medications in bold:** Top 25 medications by spend

As a pioneer in opioid management, Optum continues to collaborate with stakeholders throughout the system, leading the way towards healthier outcomes.

MANAGING PHARMACY BENEFITS STARTS WITH THE NETWORK

Nearly 40 years ago, claimants faced difficulty having their claim-related, workers' comp and auto no-fault prescriptions filled. Pharmacies often didn't know how or where to invoice those prescriptions and thus were faced with potentially not being reimbursed for dispensing the medication. The introduction of the pharmacy benefit manager (PBM) resolved the access issue by introducing the use of a pharmacy network geared towards the processing of prescription transactions for particular payers, including workers' comp and auto no-fault. PBM involvement also lowered pharmacy costs for payers as network discounts were applied to in-network transactions, reduced bill processing fees and other administrative inefficiencies, and increased access to pharmacy data. In the years that follow, emphasis on driving transactions in-network remains paramount, particularly as pharmacy costs grow to approach nearly 20% of overall medical spend.

ONCE A PRESCRIPTION IS IN-NETWORK, YOU CAN ADDRESS UTILIZATION

As network penetration increases, payers experience even lower pharmacy costs, become better equipped to holistically manage the claim, and the safety and efficacy of the claimant's medication therapy improve. Programmatic business rules, drug utilization review criteria and injury-based formularies can be more refined and widespread. Advanced network enforcement capabilities along with improvements in electronic adjudication, including connectivity from pharmacy to payer, facilitate better monitoring and measurement of data. Increased knowledge about the dispensing process and pharmacy utilization yields better clinical management throughout the care continuum. As a result, payers start to see how better pharmacy management can influence overall medical spend, a claimant's functional restoration and/or return to work and their overall health status.

MANAGING PHARMACY UTILIZATION OFTEN REQUIRES CHANGE

The ability to measure pharmacy activity allows PBMs and payers to act when the medication therapy regimen presents a concern. Identifying the need for change however, doesn't automatically mean the change will occur. Often times a lack of expertise or resources along with competing priorities result in failure to take action. Similarly, incomplete health-related information or misinformation about a claimant's entire treatment plan can cause prescribers to manage a claimant differently than they might otherwise, were more complete pharmacy information available.

To address these challenges, PBMs add a variety of outreach tools to facilitate multi-disciplined care coordination and information sharing. Pharmacist reviews, specialty-matched peer-to-peer evaluations, and the use of drug testing and monitoring (to name a few) are now deployed with greater frequency, much earlier in the claim lifecycle. When done correctly, this collaborative effort can have a dramatic effect: claimants receive the right medication at the right time, in the right dose and for the right duration. Meanwhile, payers avoid paying for the most expensive prescription; the one that should not have been paid in the first place.

THE MORE YOU KNOW, THE GREATER YOUR INFLUENCE

With cost and utilization management tools in place, the PBM metamorphosis continues. There is an even greater focus on efforts to increase understanding within the payer community. Emphasis on enabling claims management professionals to take more proactive action also take center stage. Continuing education programs, interactive resource guides, white papers and other educational tools help payers dissect and better understand pharmacy and its influence on claim outcomes. The use of statistical analysis unleashes the predictive power of pharmacy data. As data and analytics pair with clinical expertise, payers intervene earlier in the lifecycle of those claims where their professional influence is needed most. These actions further drive down costs. Importantly, because the PBM has transformed into a provider of pharmacy care services, payers experience even greater value from their program starting with the first fill and enduring all the way through claim resolution and/or settlement due to increased administrative efficiency, shorter pharmacy claim duration, fewer instances of unnecessary medical use and spend, and safer, more appropriate and cost-effective care.

Opioid analgesic statistics sources

Front cover

Optum workers' comp and auto no-fault book of business, 2015-2016

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About Optum for Workers' Compensation and Auto No-Fault

The workers' comp and auto no-fault division of Optum collaborates with our clients to deliver value beyond transactional savings while helping ensure claimants receive safe and effective clinical care. Our innovative and comprehensive medical cost management programs include pharmacy, ancillary and managed care services from first report of injury to settlement.